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Award Number: DAMD17-02-1-0139

TITLE: Molecular Markers of Estrogen Metabolism and Progression

From High-Grade Prostatic Intraepithelial Neoplasia

(HGPIN) to Prostate Cancer

PRINCIPAL INVESTIGATOR: Jay H. Fowke, Ph.D.

Fritz Parl, Ph.D. Quiyin Cai, Ph.D.

Scott Shappell, M.D., Ph.D.

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Nashville, Tennessee 37232-8300

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DAMD17-02-1-0139

MOLECULAR MARKERS OF ESTROGEN METABOLISM AND PROGRESSION FROM HIGH-GRADE PROSTATIC INTRAEPITHELIAL NEOPLASIA (HGPIN) TO PROSTATE CANCER

First Annual Report submitted March 14, 2003

This study is beginning its second full year of funded activity. All protocols for the collection of data are finalized and we have begun to recruit participants. Specific accomplishments are described in the following narrative, in parallel with the original Statement of Work.

INTRODUCTION

This work is based on a growing body of laboratory evidence that estrogens contribute to the advancement and detection of prostate cancer. Prostate tumor cells express estrogen receptors, and estrogen exposure may sustain tumor growth as androgen levels decrease with advancing age (1). It has further been shown that not all estrogens behave alike. Relative to 2-hydroxyestrone (2HE), 16HE appears bind with higher affinity to the estrogen receptor (5), and the relative balance of estrogen metabolites is determined by several enzyme activities. The CYP3A4 and CYP1B1 P-450s are responsible for converting estradiol to the 16HE or 4 HE metabolites, respectively, at the expense of 2HE production. Both CYP1B1 and CYP3A4 are expressed in prostate tissue, a polymorphism of the CYP3A4 gene in the 5' transcriptional regulatory element (CYP3A4-V) has been significantly associated with later age and advanced stage at CaP detection compared to men with the wild-type gene (6). Similarly, prostate cancer cases may be 3-fold more likely than controls to be homozygous for the CYP1B1 val allele (7). The goal of this New Investigator Award is to conduct a pilot case-control study investigating the association between molecular markers of estrogen metabolism and diagnosis of prostate cancer (stage II/III) and high-grade prostatic intraepithelial neoplasia (HGPIN), the purported precursor pathologic state to prostate cancer. We will recruit 45 men with HGPIN, 45 prostate cancer cases, and 45 healthy controls free of prostate cancer at biopsy. Genetic polymorphisms in CYP3A4 and CYP1B1 associated with estrogen metabolism will be determined from blood collected from each participant. Data regarding family history of prostate cancer and other risk factors is collected by questionnaire, and habitual dietary intake is measured by in-person interview. We hypothesize that CaP cases will have lower urinary 2HE/16HE and 2HE levels, and higher urinary 16HE, 4HE, E2 and blood E2 levels compared to HGPIN cases or healthy controls.

With the first year of this 3-year award now complete, we have achieved most of the 12-month objectives specified in our statement of work, including the obtainment of IRB approval, development of questionnaires and other data collection tools, and the recruitment of study participants. In the future project years, participant recruitment and data collection will continue,

and our analyses will determine the association between estrogen-related markers and HGPIN.

BODY

Work accomplished during the Year 1 period of this NIA encompasses Statement of Work tasks outlined in Stage 1 (Run-In: Months 1-8)) and Stage 2 (Recruitment and Data Collection: Months 9-26)). Work outlined as Stage3, Stage 4, or Stage 5 has not been completed.

Stage 1: Run-In Phase: Months 1-8:

1. Develop all questionnaires, pathology record abstraction forms, and data collection protocols

All forms were developed specifically for this project. Our risk factor questionnaire measures include: demographics; age; sex; race; marital status; education; number of children; medical history and treatment; family health history of prostate cancer; history of other cancers, exercise frequency; and smoking status. (Appendix). Our dietary assessment instrument is the Diet History Questionnaire, recently developed by the NIH and shown to have favorable reliability and validity to other established dietary assessment instruments. We had a computer-assisted program developed to guide the implementation of our dietary assessment instrument. Our Pathology Record Abstraction form records the clinic sites, dates and clinical results of all PSA, encodrine, and digital rectal exam results, ultrasound results, biopsy history and results, pathological diagnosis (HGPIN, cancer), and zone and distribution of the disease. Similarly, we record any cancer diagnosis, as well as stage and Gleason scale of cancer. We have developed Body Measurement protocols (Anthropometrics), including the methods of measuring and recording measurement of participant weight, height, sitting height, waist, and hips. Our Biospecimen Collection form records blood collection status for purposes of DNA extraction or serology, and urine specimens for estrogen metabolite measurement. All samples are aliquoted and stored frozen as necessary to meet our research objectives. Medication use is recorded on the Medication Use form. Subjects are instructed to bring all current medications and supplements to the data collection meeting, and name of the drug, dosage, and use patterns are recorded. The Interview Checklist ensures that all assigned tasks required during the interview are completed, including a review of eligibility, completion of all data collection protocols, and proper consent of participant.

2. Hire a Research Nurse

For this project, Saundra Motley, RN, was hired to serve as Project Manager. Ms. Motley is responsible for the day-to-day administration. She also has been trained to collect body size measurements using standard and systematic protocols, as well as in urine and blood collection, sample preparation, and storage protocols.

3. Pre-test questionnaires and forms

All instrument materials have been thoroughly reviewed and validated, and final versions of all assessment instruments have been produced.

4. Refine questionnaire protocols, as necessary

The Baseline Questionnaire was edited to provide a better organization to the questions. We have improved our assessment of dietary intake by developing portion size guides (Appendix), and the addition of several foods common to the Tennessee population (asparagus, okra, squash). We are conducting a sub-study to determine if completion of the dietary questionnaire at home and with a wife/partner provides substantially different food intake scores compared to our in-person interview protocol. The laptop computer program we had developed for this project initially had several 'glitches', but is now working without errors or failures.

5. Finalize IRB application and consent form, if necessary

IRB approved consent forms have been obtained from Vanderbilt University, the VA, and the US AMRMC (Appendix).

6. Develop the study data management systems, including the combination of Teleform, Microsoft Access, Epi-Info, and SAS

Our data management system continues to develop, as we recognize and incorporate new technologists into our study. We are able to rapidly identify potentially eligible men receiving care at one of the urology cancer centers through newly implemented scheduling and patient monitoring software in the clinic. This will greatly increase our efficiency to recruit urology patients in the future. New data collection protocols have been developed to fully utilize all resources. Dietary assessment data are entered directly into an ACCESS database using a computer-based dietary assessment interview program created specifically for this project. The ACCESS database may be read by SAS, and merged with other databases for the purposes of analysis. Additional data-entry programs for questionnaires and forms will follow this model, using ACCESS with subsequent transfer into SAS.

7. Become trained in all clinic-site office and administrative procedures

The PI and/or Project Manager have received tours of the urology clinic at Vanderbilt and the VA, and understand the operational and administrative procedures of this clinic.

- 8. Hire and Train Project Director in all clinic based procedures
 - See #2 above. The position of Project Director and Research Nurse were efficiently combined under Ms. Motley's position in the study.
- 9. Finalize all biological sample collection and storage procedures to be used in the study
 - All biological sample collection and storage procedures for urine and blood cells and serum are finalized. After obtaining consent, we obtain a urine and blood sample, body size measurements, and participants complete the diet questionnaire. Urine is aliquoted to 9 cryovials, and stored at -80 C. One tube of blood, 5ml (EDTA) is collected for DNA extraction. Two 5ml tubes of blood (No anticoagulants) are collected, centrifuged, and the supernate aliquoted for steroid hormone measurement.
- 10. Establish reliability of all laboratory procedures to be used

The genotyping assays for CYP3A4 and CYP1B1 are routine genotyping assays in our group with established reliability. The estrogen metabolite assays have published reliability and validity. Laboratory reliability will be determined at the time the assays are scheduled to run, during Year 2 or Year 3 of the project.

11. Establish screening procedures for men with HGPIN, prostate cancer patients, or controls.

Candidates are identified by collaborators in the urology clinics as potentially eligible for our research study. As part of standard recruitment procedures, we mail an introductory letter and brochure to candidates (Appendix). This is followed by a telephone calls (Appendix for script) intended to answer any questions and evaluate interest in the study. If interested and determined potentially eligible, a meeting is scheduled at the study center. The Project Manager confirms eligibility and obtains informed consent (Appendix for consent form) prior to data collection.

12. Order supplies necessary for biological sample collection

All supplies necessary for biological sample collection have been ordered and received.

13. Create complete manual of operations

We have created a manual of operations to organize and record every procedures and protocol in this study. All items in the Appendix are included in the Manual, as well as a copy of the original grant proposal and correspondence with DOD colleagues.

Stage 2a: Recruitment of 45 men with high grade intraepithelial neoplasia, 45 men with Stage II/III prostate cancer, and 45 men without CaP or HGPIN at biopsy: Months 8-26

Consistent with our time-line for this study, we started study recruitment in January 22, 2003. We have recruited, consented, and collected complete data from 15 participants. An additional 30 candidates are in various states of scheduling and recruitment. At this time, 100% of men approached for recruitment have agreed to participate in our study.

1. Identify 45 men with HGPIN eligible for the study from the urology clinics.

We have identified 3 men with HGPIN.

2. Identify 45 men with prostate cancer.

We have identified 7 men with prostate cancer.

3. Abstract medical records for health history and pathology data, as described in Methods section of this proposal.

We have accessed medical records and abstracted relevant prostate cancer pathology information using our pathology data form.

4. Gain informed consent

All participants are consented in an IRB approved manner.

- 5. Among those who say they are willing to participate, determine eligibility using the criteria described in the Methods Section of this proposal
 - Eligibility is determined via telephone interview, and confirmed during the in-person interview.
- 6. Enroll consecutive eligible men with confirmed HGPIN or stage II/III prostate cancer.

 All eligible HGPIN and prostate cancer patients approached for enrollment have enrolled in our study.
- 7. Ensure that the spot urine samples and blood samples are collected, processed, and stored in a -80° C freezer at the Vanderbilt University
 - All urine and blood samples are collected and processed using described protocols, then stored in a -80 C freezer at Vanderbilt University.
- 8. Collect data on lifestyle, demographics, and health (family and personal history), as outlined in proposal
 - Each participant completes a Background Questionnaire, collecting lifestyle, demographic, and medical data. This questionnaire is mailed to participants prior to the clinical visit, and then reviewed by the Project Manager at that time for completeness. Any blank questions or illogical responses are clarified at that time.
- 9. Pathology record abstractions will be performed

The Project Manager abstracts relevant medical and pathology information from the pathology report, and records this information on the Pathology Report Form. This data will be key punched into an ACCESS database for analysis.

10. Collect anthropometrics

We measure weight, height, waist, hips, and sitting height for each participant using standardized protocols as described. All body measurements are recorded on our Body Measurement Form, and will be key-punched into an ACCESS data base for analysis.

Stage 3: Data Entry, Verification and Interim Analysis, Months 12-30

- Assure that all data are immediately read into analytic databases
- Flag all outlier and illogical responses
- Verify all outlier and illogical responses, re-contacting participants, if necessary.
- Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics)

Stage 4: Laboratory Analyses, Months 24 - 30

- Transfer urine samples to the lab of Dr. Parl for estradiol and estrogen metabolite assays
- Transfer blood sample to lab of Dr. Parl for estradiol assay
- Transfer blood samples to lab of Dr. Cai for CYP1B1 and CYP3A4 genotyping assays
- Confirm quality control procedures, and repeat assays if necessary

Stage 5: Final Data Analysis, Months 30-36:

Perform exploratory analyses to test for adherence to model assumptions

- Perform any necessary data transformations to meet statistical assumptions
- Test study hypothesis
- Conduct post-hoc analyses of study data
- Prepare manuscripts
- Archive datasets for future analyses and future patient follow-up
- Plan for future studies

There has been no work accomplished within stages 3-5 of the Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS

- Development of all questionnaires and data collection forms
- IRB approvals
- Key hiring of research nurse
- Training in the collection of all data and measurements
- Preliminary testing of all data collection protocols
- Initiation of participant recruitment, including consent, recruitment, eligibility, data collection, biospecimen collection, and storage protocols.

REPORTABLE OUTCOMES

No reportable outcomes are available from this work at this time.

CONCLUSIONS

After experiencing delays with study start up due to issues around Human Subjects agreements and Recruitment protocols, this study is now on track in terms of research deliverables at the end of Year 1.

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Appendices

Appendix 1: Questionnaires

Diet History Questionnaire Background History Physical Activity

Appendix 2: Data Collection Forms

Interview Checklist Body Measurement Biological Specimen Collection Pathology

Appendix 3: Recruitment and Consent

Letter of Introduction Brochure Phone Script Vanderbilt Consent Form VA Consent Form Thank You Letter

Appendix 4: Written Protocols

Informed Consent
Patient ID and Confidentiality
Adverse Events
Questionnaires
Blood Collection
Urine Collection
Body Size Measurements

Diet History Questionnaire



GENERAL INSTRUCTIONS

 Answer each question as best you can. Estimate if you are not sure. A guess is better than leaving a blank.

CODE

BAR

- Use only a No. 2 pencil.
- Be certain to completely blacken in each of the answers.

LABEL HERE

- Erase completely if you make any changes.
- Do not make any stray marks on this form.
- If you blacken NEVER or NO for a question, please follow any arrows or instructions that direct you to the next question.

BEFORE TURNING THE PAGE, PLEASE COMPLETE THE FOLLOWING QUESTIONS.

Today's date:

| MONTH | DAY | YEAR |
|-------|----------|-----------------|
| O JAN | ĪĪ | 1998 |
| ○ FEB | |) 1999 |
| MAR | OO | ∶ ⊃ 2000 |
| O APR | \odot | 2001 |
| O MAY | 33 |) 2002 |
| JUN | 30 | |
| Ojur | 10 | |
| AUG | (3) | |
| O SEP | 9 | |
| OCT | 3 | |
| O NOV | (3) | |
| O DEC | 0 | |

In what month were

you born?

JAN
FEB
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT

O NOV

In what year were you born?

Are you male or female?

○ Male
○ Female

PLEASE DO NOT WRITE IN THIS AREA

SERIAL#

| Over the <u>past 12 months</u> , how often did you drink tomato juice or vegetable juice? | Over the past 12 months |
|--|---|
| NEVER (GO TO QUESTION 2) | 4. How often did you drink other fruit drinks (such as cranberry cocktail, Hi-C, lemonade, or Kool-Aid, diet or regular)? |
| 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day | NEVER (GO TO QUESTION 5) |
| 3-4 times per week 6 or more times per day 5-6 times per week | 1 time per month or less 1 time per day 2–3 times per month 2–3 times per day |
| 1a. Each time you drank tomato juice or vegetable juice, how much did you usually drink? | ☐ 1-2 times per week ☐ 3-4 times per week ☐ 6 or more times per day ☐ 5-6 times per week |
| Less than ³ /4 cup (6 ounces) 3/4 to 1 ¹ /4 cups (6 to 10 ounces) | 4a. Each time you drank fruit drinks, how much did you usually drink? |
| More than 1 ¹ / ₄ cups (10 ounces) | Less than 1 cup (8 ounces) 1 to 2 cups (8 to 16 ounces) |
| Over the <u>past 12 months</u>, how often did you drink orange juice or grapefruit juice? | More than 2 cups (16 ounces) 4b. How often were your fruit drinks diet or |
| NEVER (GO TO QUESTION 3) | sugar-free drinks? Almost never or never |
| 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day | ○ About 1/4 of the time ○ About 1/2 of the time ○ About 3/4 of the time |
| 3–4 times per week 6 or more times per day 5–6 times per week | Almost always or always |
| 2a. Each time you drank orange juice or grapefruit juice, how much did you usually drink? | 5. How often did you drink milk as a beverage (NOT in coffee, NOT in cereal)? (Please include chocolate milk and hot chocolate.) |
| Less than ³/₄ cup (6 ounces) √ ³/₄ to 1¹/₄ cups (6 to 10 ounces) | NEVER (GO TO QUESTION 6) |
| More than 1 ¹ / ₄ cups (10 ounces) | 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day |
| Over the <u>past 12 months</u>, how often did you drink other 100% fruit juice or 100% fruit juice mixtures (such as apple, grape, pineapple, or others)? | 3-4 times per week 5-6 times per week 6 or more times per day |
| NEVER (GO TO QUESTION 4) | 5a. Each time you drank milk as a beverage, how much did you usually drink? |
| 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day | ◯ Less than 1 cup (8 ounces) ◯ 1 to 1¹/₂ cups (8 to 12 ounces) ◯ More than 1¹/₂ cups (12 ounces) |
| 3–4 times per week 6 or more times per day 5–6 times per week | 5b. What kind of milk did you usually drink? |
| 3a. Each time you drank other fruit juice or fruit juice mixtures, how much did you usually drink? | ○ Whole milk ○ 2% fat milk ○ 1 % fat milk ○ Skim, nonfat, or ¹/2% fat milk |
| Less than ³/₄ cup (6 ounces) ³/₄ to 1¹/₂ cups (6 to 12 ounces) More than 1¹/₂ cups (12 ounces) | Soy milk Rice milk Other |
| ■ V ■ Garatica 4 appears in the next column | Curistion 6 appears on the next page |

| Ov | er the <u>p</u> | ast 12 months | 7d. | How often were these soft drinks, soda, or pop diet or sugar-free? |
|----|-----------------|--|-------------|--|
| 6. | How o | ften did you drink meal replacement, energy, | | |
| | or hig | h-protein beverages such as Instant Breakfast, | | ○ Almost never or never |
| | | e, Slimfast, Sustacal or others? | | O About 1/4 of the time |
| | | | | ○ About ¹/₂ of the time |
| , | N | EVER (GO TO QUESTION 7) | | O About 3/4 of the time |
| 1. | <i>-</i> | , | | About 14 of the time Almost always or always |
| : | \bigcirc 1 | time per month or less 0 1 time per day | | — All flost always of always |
| : | | -3 times per month 2-3 times per day | 7e. | How often were these soft drinks, soda, or pop |
| | | · - , · · | 76. | |
| : | | | | caffeine-free? |
| i | | 4 times per week 6 or more times | | |
| į | (_) 5 - | -6 times per week per day | | Almost never or never |
| į | | | | C: About 1/4 of the time |
| : | 6a. | Each time you drank meal replacement | | ○ About ¹ /2 of the time |
| ì | | beverages, how much did you usually drink? | | ○ About ³ /4 of the time |
| : | | | | C Almost always or always |
| : | | Less than 1 cup (8 ounces) | | |
| | | 1 to 11/2 cups (8 to 12 ounces) | | · · |
| 1 | | O More than 11/2 cups (12 ounces) | 8. Over | the past 12 months, did you drink beer? |
| d. | | , , , | | |
| ٧ | | • | ,ON | NO (GO TO QUESTION 9) |
| 7. | Over t | the past 12 months, did you drink soft drinks, | | |
| • | | or pop? | OY | res == |
| | , | o. pop. |) (T. | |
| | N | IO (GO TO QUESTION 8) | ll V | |
| İ | <i>\(\)</i> | 10 (00 10 4020110110) | 8a. | How often did you drink beer IN THE SUMMER? |
| 1 | O Y | TEQ. | Julia Julia | Tiow often did you dillik been in The Commerce |
| 1 | Ť | 23 | i | O NEVER |
| İ | V | | 1 | NEVER |
| | 7- | Llaverstan did vou drink aust drinks aude or | | 1 time per month or less 1 time per day |
| | 7a. | How often did you drink soft drinks, soda, or | | • |
| İ | | pop IN THE SUMMER? | | 2-3 times per month 2-3 times per day |
| - | | · | | 1–2 times per week 4–5 times per day |
| 1 | | ○ NEVER | | 3-4 times per week 6 or more times |
| | | | | |
| i | | ○ 1 time per month or less ○ 1 time per day | | |
| | | ○ 2–3 times per month ○ 2–3 times per day | 8 b. | How often did you drink beer DURING THE |
| | | | | REST OF THE YEAR? |
| | | ○ 3-4 times per week ○ 6 or more times | | |
| | | | | ○ NEVER = |
| | | • | | - |
| | 7b. | How often did you drink soft drinks, soda, or | | 1 time per month or less 1 time per day |
| 1 | | pop DURING THE REST OF THE YEAR? | | 2-3 times per month 2-3 times per day |
| ļ | | | ! ! | 1-2 times per week 4-5 times per day |
| ļ | | ○ NEVER | | ○ 3-4 times per week ○ 6 or more times ■ |
| i | | () Havair | . | ○ 5–6 times per week per day |
| į | | 1 time per month or less 1 time per day | 1 | per day |
| | | 2–3 times per month 2–3 times per day | | |
| l | | - | 8c. | Each time you drank hear, how much did you = |
| 1 | | 1-2 times per week 4-5 times per day | OC. | Each time you drank beer, how much did you |
| ļ | | 3-4 times per week 6 or more times | į : | usually drink? |
| 1 | | | | |
| | | | İ | C: Less than a 12-ounce can or bottle |
| 1 | 7c. | Each time you drank soft drinks, soda, or | | 1 to 3 12-ounce cans or bottles |
| i | | pop, how much did you usually drink? | | |
| | | | | • |
| ļ | | C Less than 12 ounces or less than 1 can or bottle | | • |
| ļ | | 12 to 16 ounces or 1 can or bottle | | |
| į | | More than 16 ounces or more than 1 can or bottle | | |

Perf

| Over the <u>past 12 months</u> 9. How often did you drink wine or wine coolers? | 11b. How often did you eat oatmeal, grits, or oth cooked cereal DURING THE REST OF THE YEAR? | | |
|---|---|--|--|
| NEVER (GO TO QUESTION 10) | O NEVER | | |
| 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day 3-4 times per week 6 or more times 5-6 times per week per day 9a. Each time you drank wine or wine coolers, | 1-6 times per year 7-11 times per year 1 time per month 2-3 times per month 1 time per week 2 times per week 5-6 times per wee 1 time per day 2 or more times per day | | |
| how much did you usually drink? Less than 5 ounces or less than 1 glass | 11c. Each time you ate oatmeal, grits, or other cooked cereal, how much did you usually eat? | | |
| ☼ 5 to 12 ounces or 1 to 2 glasses ☼ More than 12 ounces or more than 2 glasses | C Less than ³ / ₄ cup C ³ / ₄ to 1 ¹ / ₄ cups C More than 1 ¹ / ₄ cups | | |
| 10. How often did you drink liquor or mixed drinks? | | | |
| NEVER (GO TO QUESTION 11) | 12. How often did you eat cold cereal? | | |
| 1 time per month or less 1 time per day 2-3 times per month 2-3 times per day 1-2 times per week 4-5 times per day 3-4 times per week 5-6 times per week 10a. Each time you drank liquor or mixed drinks, how much did you usually drink? Less than 1 shot of liquor 1 to 3 shots of liquor More than 3 shots of liquor More than 3 shots of liquor NO (GO TO QUESTION 12) YES 11a. How often did you eat oatmeal, grits, or other | NEVER (GO TO QUESTION 13) 1-6 times per year | | |
| cooked cereal IN THE WINTER? NEVER | Almost always or always 12c. How often was the cold cereal you ate All Bran, Fiber One, 100% Bran, or Bran Buds? | | |
| 1-6 times per winter 7-11 times per winter 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 2 or more times per day | Almost never or never About ¹/₄ of the time About ¹/₂ of the time About ³/₄ of the time Almost always or always | | |
| • 🗤 | į V | | |

Chesten 12 approxs in the next column

Que was Euphasius on the hold page

| Over the past 12 months | | | 13a. Each time you ate applesauce, how much did you usually eat? | | |
|-------------------------|--------------|---|--|--|--|
| | 12 d. | How often was the cold cereal you ate some other bran or fiber cereal (such as Cheerios, Shredded Wheat, Raisin Bran, Bran Flakes, Grape-Nuts, Granola, Wheaties, or Healthy Choice)? | | C Less than ¹ /2 cu C ¹ /2 to 1 cup C More than 1 cup | |
| | | Almost never or never | 14. | How often did you eat ap | ples? |
| | | About 1/4 of the time | | · • | |
| | | ○ About 1/2 of the time | | NEVER (GO TO QUES | STION 15) |
| | | O About 3/4 of the time | : | | |
| | | Almost always or always | | 1–6 times per year | 2 times per week |
| | | | 1 | ⊕ 7–11 times per year | 3–4 times per week |
| | 12e. | How often was the cold cereal you ate any | į | 1 time per month | 5-6 times per week |
| | | other type of cold cereal (such as Corn | | 2–3 times per month | 1 time per day |
| | | Flakes, Rice Krispies, Frosted Flakes, | i | 1 time per week | 2 or more times per day |
| | | Special K, Froot Loops, Cap'n Crunch, or | | 14a Each time you ato | apples, how many did you |
| | | others)? | | usually eat? | apples, now many did you |
| | | Almost never or never | | C Less than 1 app | lo. |
| | | O About 1/4 of the time | 1 1 | 1 apple | · |
| | | About 1/2 of the time | | More than 1 app | nle · |
| | | ○ About ³ / ₄ of the time ○ Almost always or always | | . O More than 1 app | |
| | | Allifost always of always | W | | • |
| | 12f. | Was milk added to your cold cereal? | 15. | How often did you eat pe frozen)? | ears (fresh, canned, or |
| م | | -() NO (GO TO QUESTION 13) | • | • | |
| | | | 1 | — NEVER (GO TO QUE | STION 16) |
| _ | <u></u> | -○YES | | 4 | |
| Perf | | | | 1–6 times per year | 2 times per week |
| | ¥ | | | ○ 7–11 times per year | 3–4 times per week |
| | 12g. | What kind of milk was usually added? | | 1 time per month | 5-6 times per week |
| | | O 14/1 1 | | O 2-3 times per month | 1 time per day2 or more times per day |
| | • | Whole milk | | 1 time per week | 2 of more times per day |
| | | 2% fat milk 1% fat milk | | 15a Each time you ate | pears, how much did you |
| | | Skim, nonfat, or 1/2% fat milk | | usually eat? | |
| ; | | Soy milk | | , | |
| | | O Rice milk | | C Less than 1 pea | ar |
| | | Other | | 💍 1 pear | |
| | | (5) 0.00 | | More than 1 pe | ar |
| ' | 12h | Each time milk was added to your cold | $-\frac{1}{2}\sqrt{\frac{1}{2}}$ | | |
| 1 | , | cereal, how much was usually added? | , V | | |
| | | | † 16. | How often did you eat b | ananas ? |
| | | ○ Less than ¹ / ₂ cup | İ | | |
| | | ○ 1/2 to 1 cup | 1 | —) NEVER (GO TO QUE | STION 17) |
| 1 | | ○ More than 1 cup | | | ~ Ottores assumed |
| . / | ! | | | 1–6 times per year | © 2 times per week |
| ¥ | ′ | | | ○ 7–11 times per year | 3-4 times per week |
| ុ 1: | 3. How | often did you eat applesauce? | ' | 1 time per month | 5-6 times per week |
| : . í | ··· O I | NEVER (GO TO QUESTION 14) | | 2–3 times per month1 time per week | 1 time per day2 or more times per day |
| | 75 | 1–6 times per year 2 times per week | | | |
| | | | | • | |
| | | | | | |
| : | | · · | . | | |
| / | / ~ | 2–3 times per month | $\perp \vee$ | • | |
| , | | 1 time per week | i Qea | estion 17 appoars 111 in 160 | t page |
| 1.4 | · Sacuration | Complete the Committee of the Committee | <u>:</u> | • | |

Oceation 17 appears in the seed page 5

| Over the <u>past 12 months</u> | 18c. Each time you ate peaches, nectarines, or plums, how much did you usually eat? |
|---|--|
| 16a. Each time you ate bananas, how many did you usually eat? C Less than 1 banana C More than 1 banana | C Less than 1 fruit or less than ¹/₂ cup O 1 to 2 fruits or ¹/₂ to ³/₄ cup C More than 2 fruits or more than ³/₄ cup |
| | 19. How often did you eat grapes? |
| 17. How often did you eat dried fruit, such as prunes or raisins (not including dried apricots)? | NEVER (GO TO QUESTION 20) |
| NEVER (GO TO QUESTION 18) 1-6 times per year | 1-6 times per year 2 times per week 7-11 times per year 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day 19a. Each time you ate grapes, how much did you usually eat? Less than 1/2 cup or less than 10 grapes 1/2 to 1 cup or 10 to 30 grapes More than 1 cup or more than 30 grapes More than 1 cup or more than 30 grapes |
| 18. Over the <u>past 12 months</u> , did you eat peaches, nectarines, or plums? NO (GO TO QUESTION 19) YES | O NO (GO TO QUESTION 21) O YES V 20a. How often did you eat fresh cantaloupe WHEN IN SEASON? |
| 18a. How often did you eat fresh peaches, nectarines, or plums WHEN IN SEASON? NEVER 1-6 times per season 2 times per week 7-11 times per season 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 2 or more times per day 18b. How often did you eat peaches, nectarines, or plums (fresh, canned, or frozen) DURING THE REST OF THE YEAR? NEVER 1-6 times per year 2 times per week 7-11 times per year 3-4 times per week 7-11 times per year 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per day 2 or more times per day | O NEVER ○ 1-6 times per season ○ 2 times per week ○ 7-11 times per season ○ 3-4 times per week ○ 1 time per month ○ 5-6 times per week ○ 2-3 times per month ○ 1 time per day ○ 1 time per week ○ 2 or more times per day 20b. How often did you eat fresh or frozen cantaloupe DURING THE REST OF THE YEAR? ○ NEVER ○ 1-6 times per year ○ 2 times per week ○ 7-11 times per year ○ 3-4 times per week ○ 1 time per month ○ 5-6 times per week ○ 2-3 times per month ○ 1 time per day ○ 2 or more times per day |
| Question 19 appears in the next column. | Question 21 appears on the next page. |

| Over the past 12 months | 22. Over the past 12 months, did you eat strawberries? |
|--|---|
| 20c. Each time you ate cantaloupe, how much did you usually eat? Chess than 1/4 melon or less than 1/2 cup 1/4 melon or 1/2 to 1 cup More than 1/4 melon or more than 1 cup | O YES 22a. How often did you eat fresh strawberries WHEN IN SEASON? |
| 21. Over the past 12 months, did you eat melon, other than cantaloupe (such as watermelon or honeydew)? NO (GO TO QUESTION 22) YES 21a. How often did you eat fresh melon, other than cantaloupe, (such as watermelon or honeydew) WHEN IN SEASON? NEVER 1-6 times per season 2 times per week 7-11 times per season 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day 21b. How often did you eat fresh or frozen melon, | 1–6 times per season 2 times per week 7–11 times per season 3–4 times per week 1 time per month 5–6 times per week 2–3 times per month 1 time per day 1 time per week 2 or more times per day 22b. How often did you eat fresh or frozen strawberries DURING THE REST OF THE YEAR? NEVER 1–6 times per year 2 times per week 7–11 times per year 3–4 times per week 1 time per month 5–6 times per week 2–3 times per month 1 time per day 1 time per week 2 or more times per day |
| other than cantaloupe (such as watermelon or honeydew) DURING THE REST OF THE YEAR? NEVER 1-6 times per year 7-11 times per year 1 time per month 5-6 times per week 2-3 times per month 1 time per day 2 times per week 2 and times per week 2 or more times per day 21c. Each time you ate melon other than cantaloupe, how much did you usually eat? | 22c. Each time you ate strawberries, how much did you usually eat? C Less than 1/4 cup or less than 3 berries 1/4 to 3/4 cup or 3 to 8 berries More than 3/4 cup or more than 8 berries 23. Over the past 12 months, did you eat oranges, tangerines, or tangelos? NO (GO TO QUESTION 24) YES |
| Less than 1/2 cup or 1 small wedge 1/2 to 2 cups or 1 medium wedge More than 2 cups or 1 large wedge | 23a. How often did you eat fresh oranges, tangerines, or tangelos WHEN IN SEASON NEVER 1-6 times per season 2 times per week 7-11 times per season 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times |

per day

Question 24 appears to the sext pag.

| Over the past 12 months | 25. How often did you eat other kinds of fruit? |
|--|---|
| 23b. How often did you eat oranges, tangerines, or tangelos (fresh or canned) DURING THE REST OF THE YEAR? | NEVER (GO TO QUESTION 26) |
| ○ NEVER | ○ 7-11 times per year ○ 1 time per month ○ 2-3 times per month ○ 1 time per day |
| ■ | 1 time per week 2 or more times per day |
| 2–3 times per month 1 time per day 1 time per week 2 or more times per day | 25a. Each time you ate other kinds of fruit, how much did you usually eat? |
| 23c. Each time you ate oranges, tangerines, or tangelos, how many did you usually eat? | C Less than ¹/₄ cup 1/₄ to ³/₄ cup More than ³/₄ cup |
| Less than 1 fruit1 fruitMore than 1 fruit | 26. How often did you eat COOKED greens (such as spinach, turnip, collard, mustard, chard, or kale)? |
| | NEVER (GO TO QUESTION 27) |
| 24. Over the past 12 months, did you eat grapefruit? NO (GO TO QUESTION 25) YES | 1-6 times per year 2 times per week 7-11 times per year 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day |
| 24a. How often did you eat fresh grapefruit WHEN IN SEASON? | 26a. Each time you ate COOKED greens, how much did you usually eat? |
| NEVER 1-6 times per season 2 times per week 7-11 times per season 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day | Less than 1/2 cup 1/2 to 1 cup More than 1 cup 27. How often did you eat RAW greens (such as spinach, turnip, collard, mustard, chard, or kale)? (We will ask about lettuce later.) |
| 24b. How often did you eat grapefruit (fresh or canned) DURING THE REST OF THE YEAR? | NEVER (GO TO QUESTION 28) |
| NEVER 1-6 times per year 2 times per weèk | 1-6 times per year 7-11 times per year 1 time per month 2-3 times per week 1 time per month 1 time per day |
| 7–11 times per year 1 time per month 2–3 times per month 1 time per month 1 time per day 2 or more times per day | 1 time per week |
| 24c. Each time you ate grapefruit, how much did you usually eat? | Less than 1/2 cup 1/2 to 1 cup More than 1 cup |
| C Less than 1/2 grapefruit 1/2 grapefruit More than 1/2 grapefruit Out stick 25 appears in the next column | Ourstion is appears on the next page. 8 |

| Ove | r the <u>past 12 months</u> | | ou eat string beans or green inned, or frozen)? | |
|----------|--|---|---|--|
| 28. | How often did you eat coleslaw? | NEVER (GO | TO QUESTION 32) | |
| Γ | NEVER (GO TO QUESTION 29) | | | |
| | 1–6 times per year 2 times per week | 1–6 times pe | er year 💮 3–4 times per week | |
| : | 7–11 times per year 3–4 times per week 5–6 times per week | 1 time per me2–3 times per | | |
| | 2–3 times per month 1 time per day | 2-3 times per we | | |
| | 1 time per week 2 or more times per day | , Tamo por w | ook 2 or more amore per day | |
| | 28a. Each time you ate coleslaw, how much did | | e you ate string beans or green ow much did you usually eat? | |
| • | you usually eat? | · | 4. | |
| : | **. A | | nan ¹ /2 cup | |
| | Less than ¹ / ₄ cup | ○ 1/2 to 1 ○ More t | | |
| į | 1/4 to ³ /4 cup More than ³ /4 cup | Moret | man i cup | |
| | Mole than 74 cup | i | | |
| ¥ 29. | How often did you eat sauerkraut or cabbage | How often did yo frozen)? | ou eat peas (fresh, canned, or | |
| | (other than coleslaw)? | | TO QUESTION 33) | |
| | NEVER (GO TO QUESTION 30) | | 0.04 | |
| | O 4 9 0 | ○ 1-6 times pe | | |
| - :- | 1-6 times per year 2 times per week | 7–11 times p | • | |
| | 7–11 times per year 3–4 times per week 5–6 times per week | 2-3 times per | | |
| 1 | ○ 1 time per month○ 5–6 times per week○ 2–3 times per month○ 1 time per day | 1 time per w | | |
| i | 1 time per week 2 or more times per day | C Tunto por w | Con 2 of more units per cay | |
| _ | C tunic per week | 32a. Each time | e you ate peas, how much did you | |
| Peri | 29a. Each time you ate cabbage or sauerkraut, how much did you usually eat? | usually e | at? | |
| i | | | han ¹ /4 cup | |
| | C Less than 1/4 cup | € 1/4 to | | |
| ļ | ○ 1/4 to 1 cup | . O More t | than ³ /4 cup | |
| | O More than 1 cup | V | | |
| V | Have often did you got powers (front connect or | 3. Over the past 1 | 2 months, did you eat corn? | |
| 30. | How often did you eat carrots (fresh, canned, or frozen)? | O NO (GO TO | QUESTION 34) | |
| 1 | NEVER (GO TO QUESTION 31) | O YES | | |
| ! | | Y | | |
| | 7–11 times per year 3–4 times per week | | en did you eat fresh corn WHEN IN | |
| į | 1 time per month 5–6 times per week | SEASON | N? | |
| | 2–3 times per month 1 time per day | | · | |
| | ① 1 time per week | () NEVE | :R | |
| į | 30a. Each time you ate carrots, how much did you usually eat? | ○ 1–6 ti | mes per season 🔘 2 times per week times per season 🕠 3–4 times per week | |
| į | you addaily but: | | per month 5 5-6 times per week | |
| | C Less than 1/4 cup or less than 2 baby carrots | | mes per month 1 time per day | |
| 1 | 1/4 to 1/2 cup or 2 to 5 baby carrots More than 1/2 cup or more than 5 baby carrots | | e per week 2 or more times per day | |
| i | the straight framework and make a straight a manual contract. | | | |

| Over the past 12 months | 36. How often did you eat mixed vegetables? |
|---|---|
| 33b. How often did you eat corn (fresh, canned, or frozen) DURING THE REST OF THE YEAR? | NEVER (GO TO QUESTION 37) |
| O NEVER | 1–6 times per year 7–11 times per year 1 time per month 5–6 times per week 5–6 times per week |
| 1–6 times per year 7–11 times per year 3–4 times per week 1 time per month 5–6 times per week | ○ 2-3 times per month○ 1 time per day○ 2 or more times per day |
| 2–3 times per month 1 time per day 2 or more times per day | 36a. Each time you ate mixed vegetables, how much did you usually eat? |
| 33c. Each time you ate corn, how much did you usually eat? | ○ Less than ¹/₂ cup ○ ¹/₂ to 1 cup ○ More than 1 cup |
| Less than 1 ear or less than 1/2 cup 1 ear or 1/2 to 1 cup More than 1 ear or more than 1 cup | 37. How often did you eat onlons? |
| More than I ear of more than I cop | NEVER (GO TO QUESTION 38) |
| 34. Over the <u>past 12 months</u> , how often did you eat broccoli (fresh or frozen)? | 1–6 times per year 2 times per week 7–11 times per year 3–4 times per week 1 time per month 5–6 times per week |
| NEVER (GO TO QUESTION 35) | 2-3 times per month 1 time per day 1 time per week 2 or more times per day |
| 1–6 times per year 7–11 times per year 1 time per month 2 times per week 3–4 times per week 5–6 times per week | 37a. Each time you ate onions, how much did you usually eat? |
| ○ 2–3 times per month ○ 1 time per day ○ 1 time per week ○ 2 or more times per day | Less than 1 slice or less than 1 tablespoon 1 slice or 1 to 4 tablespoons |
| 34a. Each time you ate broccoli, how much did you usually eat? | More than 1 slice or more than 4 tablespoons |
| C Less than 1/4 cup 1/4 to 1 cup More than 1 cup | 38. Now think about all the cooked vegetables you ate in the past 12 months and how they were prepared. How often were your vegetables COOKED WITH some sort of fat, including oil spray? (Please do not include potatoes.) |
| 35. How often did you eat cauliflower or Brussels sprouts (fresh or frozen)? | ——— NEVER (GO TO QUESTION 39) |
| NEVER (GO TO QUESTION 36) | 1–6 times per year 2 times per week 7 7–11 times per year 3–4 times per week |
| 1-6 times per year 2 times per week 7-11 times per year 3-4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day | ○ 1 time per month ○ 2–3 times per month ○ 1 time per day ○ 2 or more times per day |
| 1 time per week 2 or more times per day 35a. Each time you ate cauliflower or Brussels | |
| sprouts, how much did you usually eat? Less than 1/4 cup | |
| 1/4 to 1/2 cup More than 1/2 cup | |

Ogenhari 3d appears in the next column

Cuestion 39 appears on the rost page 10

| Over the past 12 months | 40. Over the past 12 months, how often did you eat |
|---|--|
| 38a. Which fats were usually added to your | sweet peppers (green, red, or yellow)? |
| vegetables DURING COOKING? (Please do not include potatoes. Mark as many as apply | |
| , | 1–6 times per year 2 times per week |
| Margarine (including () Corn oil | 7-11 times per year 3-4 times per week |
| low-fat) Canola or rapeseed | |
| Oil spray, such as | |
| low-fat) Pam or others | 1 time per week 2 or more times per day |
| C Lard, fatback, or C Other kinds of oils | |
| bacon fat Some of the above | j. |
| Olive oil | did you usually eat? |
| | ○ Less than ¹/a pepper |
| 39. Now, thinking again about all the cooked | C 1/s to 1/4 pepper |
| vegetables you ate in the past 12 months, how | More than 1/4 pepper |
| often was some sort of fat, sauce, or dressing | o More than 74 pepper |
| added AFTER COOKING OR AT THE TABLE? | |
| (Please do not include potatoes.) | 41. Over the past 12 months, did you eat fresh |
| • | tomatoes (including those in salads)? |
| NEVER (GO TO QUESTION 40) | |
| | NO (GO TO QUESTION 42) |
| ○ 1–6 times per year ○ 3–4 times per week | |
| | YES |
| 1 time per month 1 time per day | |
| 2–3 times per month 2 times per day | |
| | (including those in salads) WHEN IN SEASON? |
| 39a. Which fats, sauces, or dressings were usually | |
| added AFTER COOKING OR AT THE TABL | LE? NEVER |
| (Please do not include potatoes. Mark as ma | any |
| as apply.) | 1-6 times per season 2 times per week 7-11 times per season 3-4 times per week |
| Margarine (including | 1 time per month 5–6 times per week |
| low-fat) Cheese sauce | 2-3 times per month 1 time per day |
| ○ Butter (including ○ White sauce | 1 time per week 2 or more times |
| low-fat) Other | per day |
| C Lard, fatback, or | para di la constanti di la con |
| bacon fat | 41b. How often did you eat fresh tomatoes |
| | (including those in salads) DURING THE |
| 39b. If margarine, butter, lard, fatback, or bacon fat | |
| was added to your cooked vegetables AFTER | |
| COOKING OR AT THE TABLE, how much di | |
| you usually add? | |
| | |
| O Did not usually add these | ○ 7-11 times per year ○ 3-4 times per week |
| C) Less than 1 teaspoon | 1 time per month 5-6 times per week |
| 1 to 3 teaspoons | ○ 2–3 times per month ○ 1 time per day |
| More than 3 teaspoons | 1 time per week 2 or more times |
| | per day |
| 39c. If salad dressing, cheese sauce, or white sau | |
| was added to your cooked vegetables AFTE | |
| COOKING OR AT THE TABLE, how much of | did did you usually eat? |
| you usually add? | |
| | Chess than 1/4 tomato |
| Did not usually add these | O 1/4 to 1/2 tomato |
| C Less than 1 tablespoon | ○ More than ¹ /2 tomato |
| (1) 4 to 2 toblespapes | |

Quartion 42 appears on the next page

| Ove | er the <u>past 12 months</u> | | 45. | How often did you eat Fr hash browned potatoes | • |
|-------------------|--|-----------------------------|---------------|--|---------------------------------------|
| 42 . | How often did you eat lett | uce salads (with or without | | nash browned potatoes | s, of tater tots? |
| | other vegetables)? | | [- | NEVER (GO TO QUE | STION 46) |
| | NEVER (GO TO QUES | TION 43) | | | 2 times per week |
| - ; | | | | ○ 7–11 times per year | 3-4 times per week |
| • . | 1–6 times per year | 2 times per week | | 1 time per month | 5-6 times per week |
| | → 7–11 times per year | 3-4 times per week | | 2-3 times per month | 1 time per day |
| | 1 time per month | 5-6 times per week | | 1 time per week | 2 or more times per day |
| - , • ; | 2–3 times per month | 1 time per day | | Timo por trook | · · · · · · · · · · · · · · · · · · · |
| _ | 1 time per week | 2 or more times | 1 1 | 45a Fach time you ate | French fries, home fries, |
| - ; | . Turne per week | per day | | | otatoes, or tater tots how |
| • | | per day | : | much did you usu | |
| | 42a Fach time you ate I | ettuce salads, how much | : | mash dia you aca | uny out. |
| | did you usually eat? | | | 1 ass than 10 frie | es or less than 1/2 cup |
| | ala you aboutly but | • | 1 | 10 to 25 fries or | |
| _ ; | O Less than 1/4 cup | | . [| | es or more than 1 cup |
| _ | 1/4 to 11/4 cups | | | , More than 20 m | os or more train i cap |
| - : | ○ More than 1 ¹ /4 cu | | $+$ \forall | | |
| - | More than 174 cu | sps | 46. | How often did you eat po | stato salad? |
| V | • | | 40. | | |
| ■ 43. ■ | How often did you eat sala low-fat) on salads? | ad dressing (including | | NEVER (GO TO QUE | STION 47) |
| | | | 1 | 1–6 times per year | 2 times per week |
| - - | NEVER (GO TO QUES | TION 44) | | ○ 7–11 times per year | 3-4 times per week |
| | (_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | 1 time per month | ○ 5–6 times per week |
| | 1–6 times per year | 2 times per week | | 2-3 times per month | 1 time per day |
| | 7-11 times per year | 3-4 times per week | | 1 time per week | 2 or more times per day |
| 1 | 1 time per month | 5-6 times per week | | C. I time per week | 2 of filote times per day |
| | | 1 time per day | | 46a Each time you at | potato salad, how much |
| | 2–3 times per month | | | did you usually ea | |
| _ | 1 time per week | 2 or more times per day | | did you usually ea | ic: |
| | 43a Fach time you ate | salad dressing on salads, | | ◯ Less than ¹ / ₂ cu | 2 |
| | how much did you | | | ○ 1/2 to 1 cup | P |
| | mon madirala you | accamy car. | | ○ More than 1 cup | • |
| | O Less than 2 table | spoons | | J | |
| | 2 to 4 tablespoon | | \mathbb{V} | | |
| | ○ More than 4 table | | 47. | How often did you eat ba | ked, boiled, or |
| | O More than 4 table | | | mashed potatoes? | ece |
| . V | | | | | OTION 40) |
| ■ 44. ■ | How often did you eat sw | eet potatoes or yams? | | () NEVER (GO TO QUE | STION 48) |
| · | NEVER (GO TO QUES | TION 45) | | 1-6 times per year | 2 times per week |
| | • | | | 7-11 times per year | 3-4 times per week |
| | () 1–6 times per year | 2 times per week | | 1 time per month | 5-6 times per week |
| | 7-11 times per year | 3-4 times per week | | 2-3 times per month | 1 time per day |
| | 1 time per month | 5-6 times per week | | 1 time per week | 2 or more times per day |
| | 2–3 times per month | 1 time per day | !!! | c. ramo por moon | 3 2 or more amore per car, |
| | 1 time per week | 2 or more times per day | : | 47a. Each time you ate | baked, boiled, or mashed |
| - | C. Tune per week | a z or more amos per day | | | uch did you usually eat? |
| | 44a. Each time you ate s | weet potatoes or vams. | | pointeder, nen m | |
| | how much did you u | | | 1 small potato o | r less than 1/2 cun |
| | | | | 1 medium potat | |
| | ○ 1 small potato or | less than 1/4 cup | | 1 large potato o | r more than 1 cup |
| | 1 medium potato | | | | , |
| | 1 large potato or | | İ | | |
| | Trialge potato of | more than 74 oup | | | |
| | | | | | |
| $\blacksquare V$ | • | | ¥ | | , |
| — = Ω π | caren 45 appears in the next of | alunni | Que | istion 43 ar poars on the next | ραμο |
| | 4-0-3 | | 12 | | |
| | | * | - | · | |

| | ast 12 months | | | or cheese sauce was add now much was usually add |
|-----------------------------------|--|-----------------|--------------------------------------|---|
| 47b. | How often was sour cream (including low-fat) | | en | |
| | added to your potatoes, EITHER IN COOKING | ļ | Less than 1 tabl | |
| | OR AT THE TABLE? | | 1 to 3 tablespoo | |
| | | | O More than 3 tab | lespoons |
| 1 | Almost never or never (GO TO QUESTION 47d) | | | |
| | About 1/4 of the time | | | |
| i | | 48. | How often did you eat sa | ilsa? |
| | About 3/4 of the time | į | | |
| | Almost always or always | | - NEVER (GO TO QUE | STION 49) |
| 1 | | | | |
| 47c. | Each time sour cream was added to your | | 1–6 times per year | 2 times per week |
| • | potatoes, how much was usually added? | .) | 7-11 times per year | 3-4 times per week |
| | | 1 | 1 time per month | 5-6 times per week |
| | Less than 1 tablespoon | 1 | 2–3 times per month | |
| : ! | 1 to 3 tablespoons | . | 1 time per week | 2 or more times per day |
| | More than 3 tablespoons | | 7 | () = a, a p e |
| | <u></u> | | 48a. Each time you ate | salsa, how much did you |
| -> 47d | How often was margarine (including low-fat) | | usually eat? | outou, non maon ara you |
| | added to your potatoes, EITHER IN | | accany can | |
| | COOKING OR AT THE TABLE? | | C Less than 1 tabl | osnoon |
| | COOKING OR AT THE TABLE: | | | |
| | Almost nover as nover | | 1 to 5 tablespoo | |
| | Almost never or never | $ \mathcal{M} $ | More than 5 tab | lespoons |
| | O About 1/4 of the time | 7 | | |
| | O About 1/2 of the time | 49. | How often did you eat ca | itsup? |
| • | ○ About ³ /4 of the time | I | | |
| | ○ Almost always or always | | NEVER (GO TO QUE | STION 50) |
| 470 | How often was butter (including law fet) added | | ○ 1 6 times necessar | ^ 2 times negureate |
| 47e. | How often was butter (including low-fat) added | | 1-6 times per year | 2 times per week |
| | to your potatoes, EITHER IN COOKING OR AT | | ○ 7–11 times per year | 3–4 times per week |
| | THE TABLE? | 1 | 1 time per month | ○ 5–6 times per week |
| | | 1 | O 2-3 times per month | 1 time per day |
| | Almost never or never | | 1 time per week | 2 or more times per day |
| | ○ About ¹/₄ of the time | ! | | |
| | ○ About ¹ / ₂ of the time | | 49a. Each time you ate | catsup, how much did you |
| | ○ About ³ / ₄ of the time | ! ! | usually eat? | |
| | Aimost always or always | | • 1 | |
| | | | Less than 1 teas | spoon |
| 47f. | Each time margarine or butter was added to | | 1 to 6 teaspoons | 5 |
| | your potatoes, how much was usually added? | | More than 6 tea | |
| | your pounters, were means were account account | l , i . | Cr more man e tea | |
| | ○ Never added | W | | |
| | C Less than 1 teaspoon | 50. | How often did you eat st | uffing droceing or |
| | 1 to 3 teaspoons | . 00. | dumplings? | aning, aressing, or |
| | The state of the s | | uumpimgs: | |
| | ○ More than 3 teaspoons | | ALEVED (OO TO OUE | CTION 64) |
| 4= | the standard of the standard o | | (NEVER (GO TO QUE | SHUNSIJ |
| 4/g. | How often was cheese or cheese sauce added | | | |
| | to your potatoes, EITHER IN COOKING OR AT | | (1–6 times per year | 2 times per week |
| | THE TABLE? | | 7–11 times per year | 3–4 times per week |
| | • | | 1 time per month | 5-6 times per week |
| | Almost never or never (GO TO QUESTION 48) | | 2-3 times per month | 1 time per day |
| | O About 1/4 of the time | | 1 time per week | 2 or more times per day |
| i | About 1/2 of the time | | C. Carro por trook | |
| İ | About 3/4 of the time | | 50a. Fach time you ate | stuffing, dressing, or |
| ł | About 94 or the time Almost always or always | | | much did you usually eat? |
| : | J Allinost always of always | | uumpiings, now | much did you usually eat? |
| | | | C Less than 1/2 cu | ın. |
| i 1. | | | | iP |
| Ψ | | I V | O 1/2 to 1 cup | |
| | and we further our at each and | 100 | More than 1 cup | |
| ं क्रान्त्र १ १ १ वर्ग ——————— | appears in the next colorer. | ' | estion 51 appears on the ireal | page. |
| | | 3 | | |

| Over the <u>past 12 months</u> | 53b. How often were the beans you ate refried beans, beans prepared with any type of fat, or with meat added? | |
|--|---|--|
| ■ 51. How often did you eat chili? | | |
| C NEVER (CO TO OUESTION 52) | C) Almost source or one | |
| NEVER (GO TO QUESTION 52) | Almost never or never | |
| C 4 0 % | O About 1/4 of the time | |
| ■ 0 1-6 times per year 0 2 times per week | About 1/2 of the time | |
| ■ ○ 7-11 times per year ○ 3-4 times per week | ○ About ³ /4 of the time | |
| ■ | Almost always or always | |
| ■ ○ 2-3 times per month ○ 1 time per day | | |
| ■ ○ 1 time per week ○ 2 or more times per day | | |
| | 54. How often did you eat other kinds of vegetables? | |
| 51a. Each time you ate chili, how much did you | | |
| usually eat? | NEVER (GO TO QUESTION 55) | |
| | | |
| Less than 1/2 cup | 1–6 times per year 2 times per week | |
| 1/2 to 13/4 cups | 7-11 times per year 3-4 times per week | |
| More than 13/4 cups | 1 time per month 5–6 times per week | |
| - | | |
| - V | 2-3 times per month 0 1 time per day | |
| | 1 time per week 2 or more times per day | |
| = 52. How often did you eat Mexican foods (such as | | |
| tacos, tostados, burritos, tamales, fajitas, enchiladas, | | |
| quesadillas, and chimichangas)? | 54a. Each time you ate other kinds of vegetables | |
| | how much did you usually eat? | |
| NEVER (GO TO QUESTION 53) | | |
| | C Less than 1/4 cup | |
| 1–6 times per year 2 times per week | ○ 1/4 to 1/2 cup | |
| 7–11 times per year 3–4 times per week | More than 1/2 cup | |
| ■ 1 time per month 5-6 times per week | 1 India than 72 dap | |
| | | |
| | 55. How often did you eat rice or other cooked | |
| | grains (such as bulgur, cracked wheat, or millet)? | |
| 52a. Each time you ate Mexican foods, how much | grains (such as bulgur, cracked wheat, or minor): | |
| 1.4 | NEVER (GO TO QUESTION 56) | |
| | NEVER (GO TO GOLOTION 30) | |
| Less than 1 taco, burrito, etc. | ○ 1–6 times per year ○ 2 times per week | |
| 1 to 2 tacos, burritos, etc. | 7-11 times per year 3-4 times per week | |
| More than 2 tacos, burritos, etc. | 1 time per month 5–6 times per week | |
| More triain 2 tacos, burntos, etc. | | |
| · V | 2–3 times per month 0 1 time per day | |
| - | 1 time per week 2 or more times per day | |
| ■ 53. How often did you eat cooked dried beans (such as | | |
| baked beans, pintos, kidney, blackeyed peas, lima, | 55a. Each time you ate rice or other cooked | |
| lentils, soybeans, or refried beans)? (Please don't | grains, how much did you usually eat? | |
| include bean soups or chili.) | | |
| | C Less than 1/2 cup | |
| NEVER (GO TO QUESTION 54) | () 1/2 to 11/2 cups | |
| | ○ More than 1 ¹ /2 cups | |
| 1–6 times per year 2 times per week 7–11 times per year 3–4 times per week | S more than the safe | |
| — 7-11 times per year 3-4 times per week | 55b. How often was butter, margarine, or oil | |
| () 4 time not month () 5 6 times per week | added to your rice IN COOKING OR AT | |
| 1 time per month 5-6 times per week | <u> </u> | |
| ■ ○ 2–3 times per month ○ 1 time per day | THE TABLE? | |
| 2-3 times per month 1 time per day 1 time per week 2 or more times per day 53a. Each time you ate beans, how much did you usually eat? | C. Almandaman | |
| | Almost never or never | |
| 53a. Each time you ate beans, how much | | |
| did you usually eat? | ○ About ¹ / ₂ of the time | |
| | ○ About ³ /4 of the time | |
| C Less than 1/2 cup | Almost always or always | |
| ○ 1/2 to 1 cup | | |
| More than 1 cup | | |
| — W Wide that I cup | \ | |

Overstein 54 appears in the next column.

| Ove | er the <u>past 12 months</u> | | | was added to your pancakes, a toast, how much was usually |
|-------------|---|------------|--------------------------|--|
| 5 6. | How often did you eat pancakes, waffles, or French toast? | | added? | i toast, now mach was usually |
| | toast: | | C Less than 1 tab | leennon |
| | NEVER (GO TO QUESTION 57) | | 1 to 4 tablespoo | |
| | , | | ○ More than 4 tab | · · |
| ; | | | O More than 4 tab | respooris |
| : | ○ 7–11 times per year ○ 3–4 times per week | | | |
| | 1 time per month 5-6 times per week | 57 | How often did you eat la | sagna stuffod sholls |
| | 2–3 times per month () 1 time per day | } | | oli, or tortellini? (Please do |
| | 1 time per week 2 or more times per day | : | not include spagnetti or | |
| : | | | | |
| | 56a. Each time you ate pancakes, waffles, or | | ··· (NEVER (GO TO QUE | STION 58) |
| | French toast, how much did you usually eat? | | | |
| ÷ | | | 1–6 times per year | 2 times per week |
| | Less than 1 medium piece | 1 | 7-11 times per year | 3–4 times per week |
| : | 1 to 3 medium pieces | | 1 time per month | 5–6 times per week |
| | More than 3 medium pieces | | C 2-3 times per month | C 1 time per day |
| | | | C 1 time per week | 2 or more times per day |
| i | 56b. How often was margarine (including low-fat) | | • | |
| i | added to your pancakes, waffles, or French | | | lasagna, stuffed shells, |
| ļ | toast AFTER COOKING OR AT THE TABLE? | | | i, ravioli, or tortellini, how |
| 1 | | | much did you usu | ally eat? |
| | Almost never or never | | · · · · · · | • |
| j | About 1/4 of the time | | Less than 1 cup | |
| | About 1/2 of the time | | 1 to 2 cups | |
| İ | ○ About ³ / ₄ of the time | | More than 2 cup | os . |
| | ○ Almost always or always | ١٧ | | |
| | 56c. How often was butter (including low-fat) added | 58. | How often did you eat m | acaroni and cheese? |
| | to your pancakes, waffles, or French toast AFTER COOKING OR AT THE TABLE? | | ○ NEVED (OO TO OUE | OTION 50) |
| | AFTER COOKING OR AT THE TABLE? | | NEVER (GO TO QUE | 3 110N 39) |
| | Almost never or never | | (1-6 times per year | O 2 times per week |
| • | ○ About ¹/4 of the time | 1 | ○ 7–11 times per year | 3-4 times per week |
| i | About 1/2 of the time | | 1 time per month | 5–6 times per week |
| | ○ About ³ / ₄ of the time | | 2–3 times per month | 1 time per day |
| | Almost always or always | | O 1 time per week | O 2 or more times per day |
| | 56d. Each time margarine or butter was added to | | 58a. Each time you ate | macaroni and cheese, how |
| İ | your pancakes, waffles, or French toast, how | | much did you usu | |
| | much was usually added? | | | |
| i | | | C Less than 1 cup | |
| - | Never added | | 1 to 11/2 cups | |
| | Less than 1 teaspoon | | ○ More than 11/2 of | cups . |
| 1 | 1 to 3 teaspoons | $\sqrt{1}$ | | |
| : | O More than 3 teaspoons | Y | | |
| | | 59. | How often did you eat pa | asta salad or macaroni |
| ; | 56e. How often was syrup added to your | ; ! | salad? | |
| 1 | pancakes, waffles, or French toast? | į | | |
| į | | j ; ' | () NEVER (GO TO QUE | STION 60) |
| | Almost never or never (GO TO QUESTION 57) | ; | | |
| ĺ | ○ About ¹ /4 of the time | : : | ○ 1–6 times per year | 2 times per week |
| • | ○ About ¹ / ₂ of the time | 1 | | 3-4 times per week |
| | ○ About ³ /4 of the time | ', | 1 time per month | ○ 5–6 times per week |
| 1 | Almost always or always | | C 2-3 times per month | ○ 1 time per day |
| | | | C 1 time per week | O 2 or more times per day |

| ■ Over the <u>past 12 months</u> | 61. How often did you eat bagels or English muffins? |
|---|---|
| 59a. Each time you ate pasta salad or macaroni salad, how much did you usually eat? | NEVER (GO TO INTRODUCTION TO QUESTION 62) |
| C) 1 | 1-6 times per year 2 times per week |
| ○ Less than 1/2 cup | 7-11 times per year 3-4 times per week |
| 72 to 1 cap | 1 time per month 5-6 times per week |
| More than 1 cup | 2–3 times per month () 1 time per day |
| | 1 time per week 2 or more times per day |
| 60. Other than the pastas listed in Questions 57, 58, and 59, how often did you eat pasta, spaghetti, or other noodles? | 61a. Each time you ate bagels or English muffins, how many did you usually eat? |
|) NEW (ED. (2.2. T.) | Less than 1 bagel or English muffin |
| NEVER (GO TO QUESTION 61) | 1 bagel or English muffin |
| | More than 1 bagel or English muffin |
| 1–6 times per year 2 times per week | |
| 7-11 times per year () 3-4 times per week | 61b. How often was margarine (including low-fat) |
| 1 time per month 5–6 times per week | added to your bagels or English muffins? |
| ○ 2–3 times per month ○ 1 time per day | and to your bagolo or English Halling: |
| 1 time per week 2 or more times per day | C Almost never or never |
| | About 1/4 of the time |
| 60a. Each time you ate pasta, spaghetti, or other | About 1/2 of the time |
| noodles, how much did you usually eat? | About 3/4 of the time |
| | Almost always or always |
| C Less than 1 cup | Tumost divays of always |
| 1 to 3 cups | 61c. How often was butter (including low-fat) added |
| ○ More than 3 cups | to your bagels or English muffins? |
| 60b. How often did you eat your pasta, spaghetti, or | ○ Almost never or never |
| other noodles with tomato sauce or spaghetti | About 1/4 of the time |
| sauce made WITH meat? | About 1/2 of the time |
| | About ³ /4 of the time |
| Almost never or never | Almost always or always |
| ○ About 1/4 of the time | 3 7 minost diffays of always |
| ○ About ¹ /2 of the time | 61d. Each time margarine or butter was added to |
| ○ About ³ /4 of the time | your bagels or English muffins, how much was |
| Almost always or always | usually added? |
| 60c. How often did you eat your pasta, spaghetti, or | Never added |
| other noodles with tomato sauce or spaghetti | C Less than 1 teaspoon |
| sauce made WITHOUT meat? | 1 to 2 teaspoons |
| | More than 2 teaspoons |
| Almost never or never | Wore than 2 teaspoons |
| ○ About 1/4 of the time | 61e. How often was arrow above a first it |
| About 1/2 of the time | 61e. How often was cream cheese (including |
| About ³ /4 of the time | low-fat) spread on your bagels or English muffins? |
| Almost always or always | mums; |
| 004 11- 6 - 11- | Almost never or never (GO TO INTRODUCTION |
| 60d. How often did you eat your pasta, spaghetti, or | TO QUESTION 62) |
| other noodles with margarine, butter, oil, or | ○ About 1/4 of the time |
| cream sauce? | About 1/2 of the time |
| | About 3/4 of the time |
| Almost never or never | Almost always or always |
| ○ About 1/4 of the time | y runnoct annays of always |
| About 1/2 of the time | |
| ○ About ³ / ₄ of the time | |
| Almost always or always | |

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| | - | | |
|-------------------|--|-------------|---|
| Over the <u>p</u> | ast 12 months | | Each time mayonnaise or mayonnaise-type dressing was added to your sandwich breads |
| 61f. | Each time cream cheese was added to your bagels or English muffins, how much was | | or rolls, how much was usually added? |
| | usually added? | | C Less than 1 teaspoon |
| | | | 1 to 3 teaspoons |
| | Less than 1 tablespoon | 1 | More than 3 teaspoons |
| | 1 to 2 tablespoons | # | |
| | More than 2 tablespoons | 62e. (| How often was margarine (including low-fat) added to your sandwich bread or rolls? |
| The next q | uestions ask about your intake of breads | | Almost never or never |
| | bagels or English muffins. First, we will ask | | About ¹ / ₄ of the time |
| | d you ate as part of sandwiches only. Then | i | About 1/2 of the time |
| we will ask | about all other bread you ate. | | About ³ /4 of the time |
| 00 11 | | | Almost always or always |
| | often did you eat breads or rolls AS PART OF | | |
| | WICHES (including burger and hot dog rolls)? | 621. | How often was butter (including low-fat) added to your sandwich bread or rolls? |
| | EVER (GO TO QUESTION 63) | | |
| \cap 1 | -6 times per year 2 times per week | , | Almost never or never |
| | -11 times per year 3-4 times per week | | About 1/4 of the time |
| | time per month 5-6 times per week | 1 | About 1/2 of the time |
| 1 | -3 times per month | | ○ About ³/4 of the time ○ Almost always or always |
| f . | time per week 2 or more times per day | ` | C) Allifost always of always |
| • | amo per more union por day | 62a. I | Each time margarine or butter was added to |
| 62a. | Each time you ate breads or rolls AS PART | - J | your sandwich breads or rolls, how much was |
| : | OF SANDWICHES, how many did you usually | | usually added? |
| | eat? | | |
| | | (| ○ Never added |
| | 1 slice or 1/2 roll | | C Less than 1 teaspoon |
| | 2 slices or 1 roll | | 1 to 2 teaspoons |
| İ | More than 2 slices or more than 1 roll | | |
| 62h | How often were the breads or rolls that you | | |
| 020. | used for your sandwiches white bread | 63. How off | top did you got breeds or dispersells. NOT |
| 1 | (including burger and hot dog rolls)? | | ten did you eat breads or dinner rolls, NOT RT OF SANDWICHES? |
| 1 | ○ Almost never or never | NE | VER (GO TO QUESTION 64) |
| | ○ About ¹/4 of the time | | • |
| | About 1/2 of the time | O 1-0 | 6 times per year 2 times per week |
| ! | About ³ /4 of the time | ○ 7-1 | 11 times per year 💢 3–4 times per week |
| i | Almost always or always | | me per month 5-6 times per week |
| | | | 3 times per month 0 1 time per day |
| 62c. | How often was mayonnaise or mayonnaise- type dressing (including low-fat) added to your | () 1 ti | me per week 2 or more times per day |
| 1 | sandwich bread or rolls? | | Each time you ate breads or dinner rolls, NOT |
| | | | SO CENT OF BEHINDING MES BOW DUICH CIC |

r rolls, NOT much did you usually eat?

1 slice or 1 dinner roll
 2 slices or 2 dinner rolls
 More than 2 slices or 2 dinner rolls



for 42c ary pars in the next column

About 1/4 of the time

About 1/2 of the time About 3/4 of the time Almost always or always

Almost never or never (GO TO QUESTION 62e)

| r the <u>pa</u> | ast 12 months | 64. | How often did you eat ja bagels, muffins, bread, re | |
|-----------------|---|------------|--|--|
| 63b. | How often were the breads or rolls you ate white bread? | ! | NEVER (GO TO QUE | STION 65) |
| | Almost never or never | ļ : | | 2 times per week |
| | ○ About ¹/₄ of the time | | 7-11 times per year | 3-4 times per week |
| | About 1/2 of the time | | 1 time per month | 5-6 times per week |
| | About 72 of the time About 3/4 of the time | : ! | 2-3 times per month | 1 time per day |
| | About 74 of the time | 1 | 1 time per week | 2 or more times per day |
| | | | | |
| 63c. | How often was margarine (including low-fat) added to your breads or rolls? | | 64a. Each time you ate much did you usu | jam, jelly, or honey, how ally eat? |
| | | 1 | C Less than 1 teas | spoon |
| | About 1/4 of the time | | 1 to 3 teaspoons | |
| | About ¹ / ₂ of the time | | ○ More than 3 tea | |
| | About 3/4 of the time | : | | |
| | Almost always or always | 1 5 | • | |
| | | 65. | How often did you eat pe | eanut butter or other |
| 63d. | How often was butter (including low-fat) added | | nut butter? | |
| | to your breads or rolls? | i | ○ NEVED (00 TO ÓUE | 07:01:00 |
| | (Almost pover or pover | | NEVER (GO TO QUE | STION 66) |
| | Almost never or never | | 1.6 times periods | C 2 times per week |
| | About 1/4 of the time | | 1–6 times per year | 2 times per week |
| | About 1/2 of the time | | ○ 7–11 times per year | 3-4 times per week |
| | ○ About ³ / ₄ of the time | | 1 time per month | 5–6 times per week |
| | Almost always or always | 1 . | 2–3 times per month | 1 time per day |
| 63e | Each time margarine or butter was added to | | ○ 1 time per week | 2 or more times per day |
| 000. | your breads or rolls, how much was usually | | 65a. Each time you ate | peanut butter or other nut |
| | added? | | | did you usually eat? |
| | C. Novembelded | | O 1 # 4 4-61 | |
| | Never added | | C Less than 1 tabl | |
| | O Less than 1 teaspoon | 1 1 | 1 to 2 tablespoo | · · · · · · · · · · · · · · · · · · · |
| | ○ 1 to 2 teaspoons | | O More than 2 tab | lespoons |
| | More than 2 teaspoons | $ \psi $ | | |
| 63f. | How often was cream cheese (including low-fat) added to your breads or rolls? | 66. | How often did you eat ro | ast beef or steak IN |
| | | | • | |
| | Almost never or never (GO TO QUESTION 64) | | NEVER (GO TO QUE | STION 67) |
| | ○ About 1/4 of the time | 1 | | |
| | ○ About ¹ / ₂ of the time | | 1–6 times per year | 2 times per week |
| | ○ About ³ /4 of the time | : ; | 7–11 times per year | 3-4 times per week |
| | Almost always or always | | 1 time per month | 5–6 times per week |
| | | 1 . | 2-3 times per month | 1 time per day |
| 63 g. | Each time cream cheese was added to your | | 1 time per week | 2 or more times per day |
| | breads or rolls, how much was usually added? | | | *. |
| | | | - | roast beef or steak IN |
| | Less than 1 tablespoon | , | SANDWICHES, H | ow much did you usually eat? |
| | 1 to 2 tablespoons | 1 . | • | C |
| | More than 2 tablespoons | ; | Less than 1 slic | e or less than 2 ounces |
| | | : | 1 to 2 slices or 2 | 2 to 4 ounces |
| | | | O More than 2 slice | es or more than 4 ounces |
| | | : | | |
| | | | | |
| | | 1 | | |

O restion 64 appears in the next column

Question 67 appoars on the next page.

Over the past 12 months... 67. How often did you eat turkey or chicken cold CUTS (such as loaf, luncheon meat, turkey ham, turkey salami, or turkey pastrami)? (We will ask about other turkey or chicken later.) NEVER (GO TO QUESTION 68) 1–6 times per year 2 times per week → 7–11 times per year 3–4 times per week 1 time per month 5-6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day 67a. Each time you ate turkey or chicken COLD CUTS, how much did you usually eat? Less than 1 slice 1 to 3 slices : More than 3 slices 68. How often did you eat luncheon or deli-style ham? (We will ask about other ham later.) --- NEVER (GO TO QUESTION 69) () 1–6 times per year 2 times per week ○ 3-4 times per week 1 time per month ○ 5–6 times per week 2-3 times per month 1 time per day 1 time per week 2 or more times per day 68a. Each time you ate luncheon or deli-style ham, how much did you usually eat? Less than 1 slice 1 to 3 slices More than 3 slices 68b. How often was the luncheon or deli-style ham you ate light, low-fat, or fat-free? Almost never or never About 1/4 of the time ○ About 1/2 of the time ○ About ³/₄ of the time Almost always or always



| 69. | meats (such as bologna | iding low-fat)? (Please do |
|--|--|---|
| 1 | NEVER (GO TO QUE | STION 70) |
| | 1–6 times per year 7–11 times per year 1 time per month 2–3 times per month 1 time per week | 2 times per week 3-4 times per week 5-6 times per week 1 time per day 2 or more times per day |
| | | other cold cuts or luncheo did you usually eat? |
| | Less than 1 slice1 to 3 slicesMore than 3 slice | |
| e e e e e e e e e e e e e e e e e e e | meats you ate ligi | e other cold cuts or luncheon nt, low-fat, or fat-free cold meats? (Please do not ey, or chicken cold cuts.) |
| The second secon | ○ Almost never or ○ About 1/4 of the ○ About 1/2 of the ○ About 3/4 of the ○ Almost always o | time time time |
| ¥ 70. | How often did you eat ca salads, sandwiches, or c | |
| [| NEVER (GO TO QUE | STION 71) |
| The contraction of the contracti | 1–6 times per year 7–11 times per year 1 time per month 2–3 times per month 1 time per week | 2 times per week 3-4 times per week 5-6 times per week 1 time per day 2 or more times per day |
| | 70a. Each time you ate did you usually ea | canned tuna, how much t? |
| | ○ 1/4 to 1/2 cup or 3 | p or less than 2 ounces 2 to 3 ounces p or more than 3 ounces |
| | 70b. How often was the water-packed tur | |
| | ○ Almost never or ○ About ¹/4 of the ○ About ³/4 of the ○ Almost always o | lime lime lime |

| Over the past 12 months | 73. How often did you eat ground beet in mixtures |
|--|--|
| 70a. How often was the assured tune you ate | (such as meatballs, casseroles, chili, or meatloaf)? |
| 70c. How often was the canned tuna you ate | NEVER (GO TO QUESTION 74) |
| prepared with mayonnaise or other dressing (including low-fat)? | NEVER (GO TO GOLOTION 14) |
| dressing (including low-lat)? | 1–6 times per year 2 times per week |
| () Almost never or never | 7-11 times per year 3-4 times per week |
| About 1/4 of the time | 1 time per month 5-6 times per week |
| About 1/2 of the time | 2–3 times per month 1 time per day |
| About 3/4 of the time | 1 time per week 2 or more times per day |
| Almost always or always | time per week 22 or more times per day |
| Airiost always of always | 73a. Each time you ate ground beef in mixtures, |
| | how much did you usually eat? |
| 71. How often did you eat GROUND chicken or turkey? | How made and you add any out. |
| (We will ask about other chicken and turkey later.) | Less than 3 ounces or less than 1/2 cup |
| (FFE Will dail about ballot allotter allo talkey laterly | 3 to 8 ounces or 1/2 to 1 cup |
| NEVER (GO TO QUESTION 72) | More than 8 ounces or more than 1 cup |
| C) NEVER (OU TO GOLD MONTE) | |
| () 1–6 times per year 2 times per week | V |
| 7–11 times per year 3–4 times per week | 74. How often did you eat hot dogs or frankfurters? |
| 1 time per month 5-6 times per week | (Please do not include sausages or vegetarian hot |
| 2–3 times per month 1 time per day | dogs.) |
| 1 time per week 2 or more times per day | |
| O Tel mere amos per ess, | NEVER (GO TO QUESTION 75) |
| 71a. Each time you ate GROUND chicken or | |
| turkey, how much did you usually eat? | 1–6 times per year 2 times per week |
| | 7-11 times per year 3-4 times per week |
| C Less than 2 ounces or less than 1/2 cup | 1 time per month 5-6 times per week |
| 2 to 4 ounces or 1/2 to 1 cup | ○ 2–3 times per month ○ 1 time per day |
| More than 4 ounces or more than 1 cup | 1 time per week 2 or more times per day |
| | |
| , V | 74a. Each time you ate hot dogs or frankfurters, |
| 72. How often did you eat beef hamburgers or | how many did you usually eat? |
| cheeseburgers? | |
| l , | Chess than 1 hot dog |
| NEVER (GO TO QUESTION 73) | 1 to 2 hot dogs |
| I | More than 2 hot dogs |
| 1 —6 times per year 2 times per week | |
| 7–11 times per year 3–4 times per week | 74b. How often were the hot dogs or frankfurters you |
| 1 1 time per month 0 5-6 times per week | ate light or low-fat hot dogs? |
| 2–3 times per month 0 1 time per day | (C) Almost annua a mana |
| ■ ○ 1 time per week ○ 2 or more times per day | Almost never or never |
| | About 1/4 of the time |
| 72a. Each time you ate beef hamburgers or | O About 1/2 of the time |
| cheeseburgers, how much did you usually eat? | |
| Colors than 4 paths as less than 2 cursos | Almost always or always |
| Less than 1 patty or less than 2 ounces | |
| 1 patty or 2 to 4 ounces | |
| More than 1 patty or more than 4 ounces | |
| 72b. How often were the beef hamburgers or | |
| cheeseburgers you ate made with lean ground | |
| 1 | |
| beef? | |
| ■ | |
| The state of the s | |
| About 1/4 of the time | |
| About 1/2 of the time | |
| About ³ /4 of the time | |
| ■ . / O Almost always or always | - 1 AV |

Question: 73 appears in the next column.

| Over the past 12 months | 77b. How often was the steak you ate lean steak? |
|---|---|
| 75. How often did you eat beef mixtures such as beef | ○ Almost never or never |
| stew, beef pot pie, beef and noodles, or beef | About 1/4 of the time |
| | |
| and vegetables? | About 1/2 of the time |
| | About ³ /4 of the time |
| NEVER (GO TO QUESTION 76) | Almost always or always |
| 1–6 times per year 2 times per week | |
| | 78. How often did you eat pork or beef spareribs? |
| 1 time per month 5-6 times per week | |
| 2–3 times per month 1 time per day | NEVER (GO TO QUESTION 79) |
| 1 time per week 2 or more times per day | |
| Continuo per week Continuo anno per ady | ○ 1–6 times per year ○ 2 times per week |
| 75a. Each time you ate beef stew, beef pot pie, | 7–11 times per year 3–4 times per week |
| | |
| beef and noodles, or beef and vegetables, | 1 time per month 5–6 times per week |
| how much did you usually eat? | 2–3 times per month 0 1 time per day |
| | 1 time per week 2 or more times per day |
| C Less than 1 cup | |
| ① 1 to 2 cups | 78a. Each time you ate pork or beef spareribs, how |
| More than 2 cups | much did you usually eat? |
| \mathcal{N} | Chess than 4 ribs |
| 76. How often did you eat roast beef or pot roast? | 4 to 12 ribs |
| (Please do not include roast beef or pot roast in | . 1 |
| sandwiches.) | ○ More than 12 ribs |
| | |
| NEVER (GO TO QUESTION 77) | |
| | 79. How often did you eat roast turkey, turkey cutlets, |
| | or turkey nuggets (including in sandwiches)? |
| | |
| 1 time per month 5-6 times per week | NEVER (GO TO QUESTION 80) |
| ○ 2–3 times per month ○ 1 time per day | |
| 1 time per week 2 or more times per day | 1–6 times per year 2 times per week |
| | ○ 7–11 times per year ○ 3–4 times per week |
| 76a. Each time you ate roast beef or pot roast | 1 time per month 5-6 times per week |
| (including in mixtures), how much did you | 2–3 times per month 1 time per day |
| usually eat? | 1 time per week 2 or more times per day |
| accury car. | O Tallie per week |
| Less than 2 ounces | 79a. Each time you ate roast turkey, turkey |
| | |
| 2 to 5 ounces | cutlets, or turkey nuggets, how much did |
| More than 5 ounces | you usually eat? (Please note: 4-8 turkey |
| V | nuggets = 3 ounces.) |
| 77. How often did you eat steak (beef)? (Do not include | C) Less than 2 ounces |
| steak in sandwiches) | 2 to 4 ounces |
| •••••••••••••••••••••••••••••••••••••• | More than 4 ounces |
| O NEVER (GO TO QUESTION 78) | |
| 1–6 times per year 2 times per week | 80. How often did you eat chicken as part of salads, |
| | |
| 7–11 times per year 3–4 times per week | sandwiches, casseroles, stews, or other |
| 1 time per month 5 5-6 times per week | mixtures? |
| ○ 2–3 times per month ○ 1 time per day | |
| 1 time per week 2 or more times per day | NEVER (GO TO QUESTION 81) |
| 77a. Each time you ate steak (beef), how much did | 1-6 times per year 2 times per week |
| | |
| you usually eat? | ○ 7–11 times per year ○ 3–4 times per week |
| | 1 time per month 5–6 times per week |
| C Less than 3 ounces | 2–3 times per month 1 time per day |
| √ √ √ 3 to 7 ounces | 1 time per week 2 or more times per day |
| ✓ More than 7 ounces | Y |
| Cr. ston. Ps appears in the med relation | Question 61 supears on the rock page |
| | 21 |

| Over the <u>past 12 months</u> | 82. How often did you eat baked ham or ham steak? |
|--|--|
| 80a. Each time you ate chicken as part of salads, | NEVER (GO TO QUESTION 83) |
| sandwiches, casseroles, stews, or other | |
| mixtures, how much did you usually eat? | 1-6 times per year 2 times per week |
| | ○ 7-11 times per year ○ 3-4 times per week |
| ■ Cless than 1/2 cup ■ 1/2 to 11/2 cups | 1 time per month 5 5-6 times per week |
| ■ More than 11/2 cups | 2-3 times per month 1 time per day |
| ■ More than 172 cups | 1 time per week 2 or more times per day |
| • | 82a. Each time you ate baked ham or ham steak, |
| ■ 81. How often did you eat baked, broiled, roasted, | how much did you usually eat? |
| stewed, or fried chicken (including nuggets)? | Thorr maon did you disdaily eatr |
| (Please do not include chicken in mixtures.) | Less than 1 ounce |
| • | 1 to 3 ounces |
| NEVER (GO TO QUESTION 82) | More than 3 ounces |
| | |
| 1–6 times per year 2 times per week | Y · |
| 7–11 times per year 3–4 times per week | 83. How often did you eat pork (including chops, roasts, |
| 1 time per month 5-6 times per week | and in mixed dishes)? (Please do not include ham. |
| 2–3 times per month 0 1 time per day | ham steak, or sausage.) |
| 1 time per week 2 or more times per day | |
| 81a. Each time you ate baked, broiled, roasted, | NEVER (GO TO QUESTION 84) |
| stewed, or fried chicken (including nuggets), | |
| how much did you usually eat? | ○ 1–6 times per year ○ 2 times per week |
| tion much did you askally eat? | 7-11 times per year 3-4 times per week |
| Less than 2 drumsticks or wings, 1 breast | 1 time per month 5-6 times per week |
| or thigh, or less than 4 nuggets | 2-3 times per month 1 time per day |
| 2 drumsticks or wings, 1 breast or thigh, | 1 time per week 2 or more times per day |
| or 4 to 8 nuggets | 83a. Each time you ate pork, how much did you |
| ■ More than 2 drumsticks or wings, 1 breast | usually eat? |
| or thigh, or more than 8 nuggets | January Suit |
| | Chess than 2 ounces or less than 1 chop |
| 81b. How often was the chicken you ate fried | 2 to 5 ounces or 1 chop |
| chicken (including deep fried) or chicken | ○ More than 5 ounces or more than 1 chop |
| nuggets? | 1 W |
| ○ Almost never or never | 9 Howard H. |
| About 1/4 of the time | 84. How often did you eat gravy on meat, chicken, |
| About 1/2 of the time | potatoes, rice, etc.? |
| About 3/4 of the time | NEVER (GO TO QUESTION 85) |
| Almost always or always | SHEATINGO TO MOES HOM 92) |
| | 1-6 times per year |
| 81c. How often was the chicken you ate WHITE | 7-11 times per year 3-4 times per week |
| meat? | 1 time per month 5-6 times per week |
| | 2–3 times per month 1 time per day |
| Almost never or never | 1 time per week 2 or more times per day |
| About 1/4 of the time | l a similar por day |
| About 1/2 of the time | 84a. Each time you ate gravy on meat, chicken, |
| About ³ /4 of the time | potatoes, or rice, etc., how much did you |
| Almost always or always | usually eat? |
| 81d. How often did you eat chicken WITH skin? | |
| ord. Flow often did you eat chicken with skin? | Cless than 1/8 cup |
| Almost never or never | ○ 1/s to 1/2 cup |
| About 1/4 of the time | ○ More than 1/2 cup |
| About 1/2 of the time | |
| About 3/4 of the time | |
| Almost always or always | $ \hat{\mathbf{y}} $ |
| Continue to the continue of the next column | ; · · |
| · · · · · · · · · · · · · · · · · · · | Cupstion 85 inpoars on the next page |

Question 85 impears on the next page

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| Ov | er the <u>past 12 months</u> | | : | 87a. | Each time you a | ite sausage, h ow much did yo |
|------|--|---------------------------------|-----|-----------------|---|--|
| 85. | How often did you eat li | ver (all kinds) or liverwurst? | i | | usually eat? | • |
| | | | | | Chess than 1 pa | atty or 2 links |
| .: - | | ESTION 86) | | | 1 to 3 patties of | or 2 to 5 links |
| 1 | | | i | | More than 3 pa | |
| : | 1–6 times per year | 2 times per week | Ì | | more unante pi | atties of 5 lifts |
| : | 7-11 times per year | 3-4 times per week | ; | 87b. | How often was t | he sausage you ate light, |
| | 1 time per month | ○ 5–6 times per week | ! | . 1 | low-fat, or lean | salisana? |
| | 2–3 times per month | ○ 1 time per day | i | | | ouddage: |
| | 🥠 1 time per week | 2 or more times per day | : | | Almost never o | or never |
| | | • | 1 | , | About 1/4 of the | |
| | 85a. Each time you ate | e liver or liverwurst, how | | | About 1/2 of the | |
| | much did you usu | ally eat? | | , | About 3/4 of the | The state of the s |
| | | | • | | Almost always | - |
| | Less than 1 our | nce | : | | · | o. umays |
| | 1 to 4 ounces | | | | | |
| | More than 4 our | nces | 88. | How of | ten did vou eat f | ish sticks or fried fish |
| | | | | (includi | ng fried seafood | or shellfish)? |
| 3. | | | | , | • | |
| 86. | How often did you eat ba | acon (including low-fat)? | | () NE | VER (GO TO QUI | ESTION 89) |
| | NEVER (GO TO QUE | STION 87) | 1 | (*) 1. 4 | 6 times per year | C 28 |
| 1 | | , | 1 | | 11 times per year | 2 times per week |
| • | 1–6 times per year | 2 times per week | | | me per month | O 3-4 times per week |
| , | ○ 7–11 times per year | 3-4 times per week | | | | ○ 5–6 times per week |
| ;. | 1 time per month | 5-6 times per week | : ! | | 3 times per month | |
| į | 2-3 times per month | 1 time per day | | - 1 to | me per week | 2 or more times per day |
| • | 1 time per week | 2 or more times per day | | 88a. E | ach time you at | e fish sticks or fried fish, ho |
| ŀ | 86a Each time you ate | bacon, how much did you | | n | nuch did you ust | ually eat? |
| • | usually eat? | bacon, now mach ala you | ! | | T. 1 # 0 | |
| 1 | accan, car. | | | | | nces or less than 1 fillet |
| ! | C Fewer than 2 sli | ces | | | 2 to 7 ounces o | |
| | 2 to 3 slices | | | (| ∴ More than 7 ou | nces or more than 1 fillet |
| | More than 3 slice | PC | V | | | |
| į | O more triain o bilo. | | 89. | How off | on did you ont fi | -h |
| : | 86b. How often was the | bacon you ate light, low-fat, | 03. | NOT EE | RIED (including s | sh or seafood that was |
| : | or lean bacon? | bassing out ato light, fow-lat, | | NOI FR | deb (including s | sneimsn)? |
| 1 | | | | NEV | /FR (GO TO THE | INTRODUCTION TO |
| : | Almost never or | never | | | ESTION 90) | WINOBOCTION TO |
| | About 1/4 of the t | • | | | 2011011007 | |
| : | About 1/2 of the t | | | ⊜ 1_6 | times per year | 2 times per week |
| • | About 3/4 of the | | ļ | | 1 times per year | |
| ÷ | Almost always o | | | | ne per month | 3-4 times per week |
| | , | · umayo | | | times per month | 5-6 times per week |
| 1 | | | | | ne per week | 1 time per day |
| 87. | How often did you eat sa | usage (including low-fat)? | | | | 2 or more times per day |
| | ANEVED (CO TO OUT | STION 80) | i | 89a. E | ach time you ate | e fish or seafood that was |
| | NEVER (GO TO QUES | 511ON 88) | İ | n | ot fried, how mu | uch did you usually eat? |
| : | 1–6 times per year | 🔾 2 times per week | ; | C | Less than 2 our | nces or less than 1 fillet |
| i | ○ 7–11 times per year | 3–4 times per week | İ | | 2 to 5 ounces of | |
| 1 | 1 time per month | 5-6 times per week | : | | | nces or more than 1 fillet |
| : | 2-3 times per month | ① 1 time per day | ļ | • | , a aran o our | |
| : | 🐧 1 time per week | 2 or more times per day | | | a | |
| | • • • • | | ; | | | |

Чыського 83 арржагз ів чес пехі column.

Perroduction to Question an approximate next page. 23

| - |
|----|
| ٠. |
| ^ |

Over the past 12 months...

Now think about all the meat, poultry, and fish you ate in the <u>past 12 months</u> and how they were prepared.

90. How often was oil, butter, margarine, or other fat used to FRY, SAUTE, BASTE, OR MARINATE any meat, poultry, or fish you ate? (Please do not include deep frying.)

O NEVER (GO TO QUESTION 91)

| 🥠 1–6 times per year | 2 times per week |
|----------------------|------------------------------------|
| 7-11 times per year | 3-4 times per week |
| 1 time per month | 5-6 times per week |
| 2-3 times per month | 1 time per day |
| 1 time ner week | 2 or more times per day |

90a. Which of the following fats were regularly used to prepare your meat, poultry, or fish? (Mark all that apply.)

| Margarine (including | Corn oil |
|---------------------------------------|------------------------|
| low-fat) | O Canola or rapeseed o |
| Butter (including | Oil spray, such as Par |
| low-fat) | or others |
| C Lard, fatback, or | Other kinds of oils |
| bacon fat | None of the above |

91. How often did you eat tofu, soy burgers, or soy meat-substitutes?

O NEVER (GO TO QUESTION 92)

Olive oil

| 1–6 times per year | 2 times per week |
|------------------------|--------------------------|
| | ○ 3–4 times per week |
| 1 time per month | |
| 2–3 times per month | 1 time per day |
| 1 time per week | 2 or more times per day |
| 91a. Each time you ate | tofu, soy burgers, or so |

91a. Each time you ate tofu, soy burgers, or soy meat-substitutes, how much did you usually eat?

| C Less than 1/4 cup or less than 2 ounces |
|---|
| |
| O More than 1/2 cup or more than 4 ounces |
| |

92. Over the past 12 months, did you eat soups?

| N | IO (GO TO QUESTION 93) |
|--------------|--|
| √ Y | ES |
| | How often did you eat soup DURING THE WINTER? |
| | ○ NEVER |
| | 1-6 times per winter 7-11 times per winter 3-4 times per week 5-6 times per week 2-3 times per month 1 time per week 2 or more times per day |
| 92b. | How often did you eat soup DURING THE REST OF THE YEAR? |
| |) NEVER |
| | 1–6 times per year 7–11 times per year 1 time per month 2–3 times per month 1 time per week 2 times per week 5–6 times per week 1 time per day 2 or more times per day |
| 92 c. | Each time you ate soup, how much did you usually eat? |
| | Less than 1 cup1 to 2 cupsMore than 2 cups |
| 92d. | How often were the soups you ate bean soups? |
| | Almost never or never About 1/4 of the time About 1/2 of the time About 3/4 of the time Almost always or always |
| 92e. | How often were the soups you ate cream soups (including chowders)? |
| | Almost never or never About ¹/4 of the time About ¹/2 of the time About ³/4 of the time Almost always or always |

| Over the past 12 months | 94a. Each time you ate crackers, how many did you usually eat? |
|---|--|
| 92f. How often were the soups you ate tomato or | you addainy out: |
| vegetable soups? | ○ Fewer than 4 crackers |
| | () 4 to 10 crackers |
| Almost never or never | More than 10 crackers |
| ○ About 1/4 of the time | () Wore than to clackers |
| About 1/2 of the time | |
| About 3/4 of the time | 95. How often did you eat corn bread or corn muffins? |
| Almost always or always | 95. How often did you eat corn bread or corn muffins? |
| 7 milost amays of amays | (C. NEVER (GO TO QUESTION 96) |
| 92g. How often were the soups you ate broth soups | NEVER (GO TO QUESTION 90) |
| (including chicken) with or without noodles or | C 4 Climan narrows (2) Oliman narrowski |
| rice? | (, 1–6 times per year 2 times per week |
| 1100: | 7–11 times per year 3–4 times per week |
| Almost never or never | 1 time per month 5–6 times per week |
| About 1/4 of the time | 2–3 times per month 1 time per day |
| | 1 time per week 2 or more times per day |
| About 1/2 of the time | A |
| About 3/4 of the time | 95a. Each time you ate corn bread or corn |
| ○ Almost always or always | muffins, how much did you usually eat? |
| | |
| 03 How often did you got minne? | C Less than 1 piece or muffin |
| 93. How often did you eat pizza? | 1 to 2 pieces or muffins |
| ALCIVED (OO TO OMEOTION OA) | More than 2 pieces or muffins |
| | $ \mathcal{N} $ |
| | 00 11 |
| · · · · · · · · · · · · · · · · · · · | 96. How often did you eat biscuits? |
| 7-11 times per year 3-4 times per week | AIRUPD (OO TO OUTOTION OF) |
| 1 time per month 5-6 times per week | NEVER (GO TO QUESTION 97) |
| O 2–3 times per month O 1 time per day | |
| ○ 1 time per week ○ 2 or more times per day | 1–6 times per year 2 times per week |
| 020 Each time you at a nine how much did | ○ 7–11 times per year ○ 3–4 times per week |
| 93a. Each time you ate pizza, how much did you | 1 time per month 5-6 times per week |
| usually eat? | |
| O Loop than 4 allow and on the A solution | 1 time per week 2 or more times per day |
| Less than 1 slice or less than 1 mini pizza | |
| 1 to 3 slices or 1 mini pizza | 96a. Each time you ate biscuits, how many did you |
| ○ More than 3 slices or more than 1 mini pizza | usually eat? |
| O2h How often did ask nime with | , |
| 93b. How often did you eat pizza with pepperoni, | Fewer than 1 biscuit |
| sausage, or other meat? | 1 to 2 biscuits |
| | More than 2 biscuits |
| Almost never or never | |
| About 1/4 of the time | |
| About 1/2 of the time | 97. How often did you eat potato chips, tortilla chips, |
| About 3/4 of the time | or corn chips (including low-fat, fat-free, or |
| ○ Almost always or always | low-salt)? |
| | |
| ¥ | NEVER (GO TO QUESTION 98) |
| 94. How often did you eat crackers? | |
| | |
| NEVER (GO TO QUESTION 95) | 7–11 times per year 3–4 times per week |
| | ☼ 1 time per month ☼ 5–6 times per week |
| | ○ 2–3 times per month ○ 1 time per day |
| ○ 7–11 times per year ○ 3–4 times per week | C 1 time per week C 2 or more times per day |
| () 1 time per month () 5-6 times per week | |
| 2–3 times per month 1 time per day | |
| 1 time per week 2 or more times per day | |
| | |

 $Q_{\rm C}$ is upon 95 appears in the next column

A Omestion of appears or more at page

| The past 12 months | ega. Each time you ate pretzels, how many did |
|--|--|
| 970. Each time you ate material abline 4 vittle | you usually eat? |
| 97a. Each time you ate potato chips, tortilla | |
| chips, or corn chips, how much did you | Fewer than 5 average twists |
| usually eat? | |
| | More than 20 average twists |
| ■ | |
| ■ 10 to 25 chips or 1 to 2 cups | |
| ■ More than 25 chips or more than 2 cups | 100. How often did you got mannets and and |
| s | 100. How often did you eat peanuts, walnuts, seeds, or |
| 97b. How often were the chips you ate Wow chips | other nuts? |
| the same simple you are trott offipo | |
| or other chips made with fat substitute (Olean | NEVER (GO TO QUESTION 101) |
| or Olestra)? | |
| | □ 1-6 times per year |
| Almost never or never About 1/4 of the time About 1/2 of the time About 3/4 of the time | 7-11 times per year 3-4 times per week |
| About 1/4 of the time | 1 time per month 5–6 times per week |
| About 1/2 of the time | 2-3 times per month 1 time per day |
| About ³ / ₄ of the time | |
| Almost always or always | 1 time per week 2 or more times per day |
| Annost always or always | 400- 5 1 1 |
| • | 100a. Each time you ate peanuts, walnuts, |
| | seeds, or other nuts, how much did you |
| low-fat or fat-free chips? | usually eat? |
| 1 | |
| Almost never or never | C Less than 1/4 cup |
| ■ About ¹ /4 of the time | O 1/4 to 1/2 cup |
| About 1/2 of the time | More than 1/2 cup |
| ■ About ³ /4 of the time | More than 72 cup |
| Almost always or always | |
| = | 101 How often did you got an army blat wastely |
| . | 101. How often did you eat energy, high-protein, or |
| ■ 98. How often did you eat popcorn (including low-fat)? | breakfast bars such as Power Bars, Balance, Clif, or |
| - 50. Flow often did you ear popcorti (including low-lat)? | others? |
| NEVER (GO TO QUESTION 99) | |
| NEVER (GO TO QUESTION 99) | NEVER (GO TO QUESTION 102) |
| 0.4.08 | |
| ■ | 1–6 times per year 2 times per week |
| ■ ○ 7–11 times per year ○ 3–4 times per week | ○ 7–11 times per year ○ 3–4 times per week |
| ■ ○ 1 time per month ○ 5–6 times per week | 1 time per month 5–6 times per week |
| ■ ○ 2–3 times per month ○ 1 time per day | 2–3 times per month 1 time per day |
| ■ ○ 1 time per week ○ 2 or more times per day | 1 time per week 2 or more times per day |
| • | 2 of more times per day |
| 98a. Each time you ate popcorn, how much did you | 101a. Each time you ate energy, high-protein. |
| usually eat? | |
| - Goddiny Cat. | or breakfast bars, how much did you |
| O Less than 0 arms assured | usually eat? |
| Case than 2 cups, popped | |
| 2 to 5 cups, popped | C Less than 1 bar |
| ■ O More than 5 cups, popped | 1 bar |
| | More than 1 bar |
| • <i>,</i> ¥ | A say |
| 99. How often did you eat pretzels? | |
| | 102 How often did you got veget (NOT including |
| NEVER (GO TO QUESTION 100) | 102. How often did you eat yogurt (NOT including |
| i | frozen yogurt)? |
| 1 1-6 times per year . (2 times per year | NEVED (OC TO COMPANY) |
| 1–6 times per year 2 times per week | NEVER (GO TO QUESTION 103) |
| 7–11 times per year 3–4 times per week | |
| ■ ○ 1 time per month ○ 5–6 times per week | 1-6 times per year 2 times per week |
| 2–3 times per month 1 time per day | ○ 7–11 times per year ○ 3–4 times per week |
| 1 time per week 2 or more times per day | 1 time per month 5-6 times per week |
| 1 | |
| - - | 2-3 times per month 1 time per day |
| . V | 1 time per week 2 or more times per day |
| | Y |
| ■ 19 estima 160 appears in the next column. | Question 173 appears on the real page |
| • | 26 |

| Over the pas | st 12 months | 104c. How often was the cheese you ate fat-free | | | |
|----------------------------|---|---|--|--|--|
| 102a. | Each time you ate yogurt, how much did | cheese? | | | |
| | you usually eat? | Almost never or | rnever | | |
| | | ○ About 1/4 of the | | | |
| | C Less than 1/2 cup or less than 1 container | ○ About 1/2 of the | | | |
| | ○ 1/2 to 1 cup or 1 container | About ³ / ₄ of the time | | | |
| | More than 1 cup or more than 1 container | Almost always | | | |
| | . <u>#</u> | | · | | |
| 103. How ofte low-fat)? | en did you eat cottage cheese (including ? | 105. How often did you eat frices (including low-fat o | ozen yogurt, sorbet, or r fat-free)? | | |
| (; NE) | VER (GO TO QUESTION 104) | NEVER (GO TO QUE | STION 106) | | |
| 1–6 | times per year 2 times per week | 1.64: | | | |
| | 1 times per year 3-4 times per week | 1–6 times per year | 2 times per week | | |
| | me per month 5-6 times per week | ○ 7–11 times per year | 3-4 times per week | | |
| | times per month 1 time per day | 1 time per month | 5−6 times per week | | |
| 1 | | 2–3 times per month | ① 1 time per day | | |
| V _a z i un | me per week 2 or more times per day | 1 time per week | 2 or more times per day | | |
| 103a. | Each time you ate cottage cheese, how much did you usually eat? | | e frozen yogurt, sorbet, or did you usually eat? | | |
| i | C Less than 1/4 cup | Less than 1/2 ou | p or less than 1 scoop | | |
| • | ○ 1/4 to 1 cup | 1/2 to 1 cup or 1 | to 2 seesan | | |
| | ○ More than 1 cup | More than 1 our | or more than 2 scoops | | |
| V. | | wore than I cup | or more man 2 scoops | | |
| 104. How ofte including | en did you eat cheese (including low-fat; g on cheeseburgers or in sandwiches or subs)? | 106. How often did you eat icc sherbet (including low-fa | e cream, ice cream bars, or it or fat-free)? | | |
| O NEV | /ER (GO TO QUESTION 105) | NEVER (GO TO QUE | STION 107) | | |
| ○ 1–6 | times per year 2 times per week | ○ 1–6 times per year | 2 times per week | | |
| | 1 times per year 3-4 times per week | 7-11 times per year | 3-4 times per week | | |
| | ne per month 5-6 times per week | 1 time per month | • | | |
| | times per month 1 time per day | 2-3 times per month | 5-6 times per week | | |
| | ne per week 2 or more times per day | 1 time per week | 1 time per day2 or more times per day | | |
| | | Tunio per week | 2 or more times per day | | |
| 104a. | Each time you ate cheese, how much did you usually eat? | 106a. Each time you ato or sherbet, how i | e ice cream, ice cream bars much did you usually eat? | | |
| • | C Less than 1/2 ounce or less than 1 slice | / Loca than 1/a and | o or less than 1 scoop | | |
| : | ○ 1/2 to 11/2 ounces or 1 slice | 1/2 to 41/2 ave - | o or less than 1 scoop | | |
| ! | More than 11/2 ounces or more than 1 slice | 1/2 to 11/2 cups of More than 11/2 c | ups or more than 2 scoops | | |
| 104b. | How often was the cheese you ate light or low-fat cheese? | 106b. How often was th low-fat, or fat-fre | e ice cream you ate light, e ice cream or sherbet? | | |
| ! | Almost never or never | C Almost assessed | | | |
| | About 1/4 of the time | Almost never or | | | |
| | | About 1/4 of the t | | | |
| İ | About 1/2 of the time | C About 1/2 of the t | | | |
| į | About 3/4 of the time | About 3/4 of the t | | | |
| • | Almost always or always | ○ Almost always or | r al ways | | |
| ! | | | | | |
| : | | | | | |

Fr - stion 196 appears in the next column

. . .

Quarties 1.7 or pears on the 1.34 page 27

| * |
|----|
| ŏ |
| Ξ, |
| |

| Over the <u>past 12 months</u> | 109. How often did you eat doughnuts, sweet rolls, Danish, or pop-tarts? |
|---|---|
| 107. How often did you eat cake (including low-fat or fat-free)? | |
| orial-nee)? | NEVER (GO TO QUESTION 110) |
| | ○ 1–6 times per year ○ 2 times per week ○ 7–11 times per year ○ 3–4 times per week |
| ■ 1–6 times per year 2 times per week | · · · · · · · · · · · · · · · · · · · |
| ■ 7–11 times per year 3–4 times per week | |
| 1 time per month 5–6 times per week | |
| · · · · · · · · · · · · · · · · · · · | 1 time per week 2 or more times per day |
| | 400s Fash thus and the state of the |
| 1 time per week 2 or more times per day | 109a. Each time you ate doughnuts, sweet rolls, |
| 107a. Each time you ate cake, how much did you usually eat? | Danish, or pop-tarts, how much did you usually eat? |
| usually eat? | 10 10 10 10 10 10 10 10 10 10 10 10 10 1 |
| The section 1 medium since | Less than 1 piece |
| Less than 1 medium piece | 1 to 2 pieces |
| 1 medium piece | More than 2 pieces |
| ■ O More than 1 medium piece | |
| 407h Hannafton ann tha air an t-11 t 4 4 | |
| 107b. How often was the cake you ate light, low-fat, or fat-free cake? | 110. How often did you eat sweet muffins or dessert breads (including low-fat or fat-free)? |
| ■ | NEVER (GO TO QUESTION 111) |
| About 1/4 of the time | O NEVEN (OO TO GOESTION TIT) |
| About 1/2 of the time | 1–6 times per year 2 times per week |
| About 72 of the time | 7-11 times per year 3-4 times per week |
| About 74 of the time Almost always or always | 1 time per month 5–6 times per week |
| - Vallost always of always | |
| V | |
| ■ 108. How often did you eat cookies or brownies | 1 time per week 2 or more times per day |
| (including low-fat or fat-free)? | 110a. Each time you ate sweet muffins or dessert breads, how much did you usually eat? |
| NEVER (GO TO QUESTION 109) | breads, now mach did you doubly eat: |
| • | ○ Less than 1 medium piece |
| ■ 1–6 times per year | 1 medium piece |
| ■ 7–11 times per year 3–4 times per week | More than 1 medium piece |
| ■ 1 time per month 5-6 times per week | y wore than I medium piece |
| ■ 2–3 times per month ① 1 time per day | 110b. How often were the sweet muffins or dessert |
| 1 time per week 2 2 or more times per day | breads you ate light, low-fat, or fat-free |
| 108a. Each time you ate cookies or brownies, how | sweet muffins or dessert breads? |
| much did you usually eat? | ○ Almost never or never |
| - moon die you addany eat: | · · · · · · · · · · · · · · · · · · · |
| Less than 2 cookies or 1 small brownie | About 1/4 of the time |
| 2 to 4 cookies or 1 medium brownie | About 1/2 of the time |
| More than 4 cookies or 1 large brownie | About ³ /4 of the time |
| | Almost always or always |
| 108b. How often were the cookies or brownies you ate light, low-fat, or fat-free cookies or brownies? | 111. How often did you eat fruit crisp, cobbler, or strudel? |
| • | NEVER (GO TO QUESTION 112) |
| ■ | · · · · · · · · · · · · · · · · · · · |
| About 1/4 of the time | 1–6 times per year 2 times per week |
| About 1/2 of the time | 7-11 times per year 3-4 times per week |
| About 1/2 of the time | 1 time per month 5–6 times per week |
| | |
| ♠ Almost always or always | 2-3 times per month 1 time per day |
| | 1 time per week 2 or more times per day |
| . V | I W |
| • One of an difference manifold and a second | Francisco 410 marsh and San |
| Ourse in 16 rappears in the road commit | Question 111 appears on the next page. |
| | 28 |

| Over the <u>past 12 months</u> | 112e. How often were the pies you ate pecan pie? |
|---|---|
| 111a. Each time you ate fruit crisp, cobbler, or | ○ Almost never or never |
| strude! how much did you usually eat? | About 1/4 of the time |
| | O About 1/2 of the time |
| C Less than 1/2 cup | About 3/4 of the time |
| ¹ /2 to 1 cup | Almost always or always |
| ○ More than 1 cup | s vancet unterjo di untuju |
| | 113. How often did you eat chocolate candy? |
| 12. How often did you eat pie? | • |
| NEVER (GO TO QUESTION 113) | NEVER (GO TO QUESTION 114) |
| | 1–6 times per year 2 times per week |
| 1-6 times per year 2 times per week | 7-11 times per year 3-4 times per week |
| 7-11 times per year 3-4 times per week | 1 time per month 5–6 times per week |
| 1 time per month 5–6 times per week | 2–3 times per month 1 time per day |
| 2–3 times per month 0 1 time per day | 1 time per week 2 or more times per day |
| ☐ 1 time per week ☐ 2 or more times per day | 3 2 of filore times per day |
| | 113a. Each time you ate chocolate candy, how |
| 112a. Each time you ate pie, how much did you usually eat? | much did you usually eat? |
| | C Less than 1 average bar or less than 1 ounce |
| C Less than 1/8 of a pie | 1 average bar or 1 to 2 ounces |
| ○ About ¹/s of a pie | More than 1 average bar or more than 2 ounces |
| ○ More than ¹/s of a pie | word than a average bar of more than 2 outless |
| | |
| The next form assertions selections and about the little of | 114. How often did you eat other candy? |
| The next four questions ask about the kinds of pie | |
| you ate. Please read all four questions before | NEVER (GO TO QUESTION 115) |
| answering. | |
| 445 | 1–6 times per year 2 times per week |
| 112b. How often were the pies you ate fruit pie | ○ 7–11 times per year ○ 3–4 times per week |
| (such as apple, blueberry, others)? | 1 time per month 5-6 times per week |
| | 2-3 times per month 1 time per day |
| Almost never or never | 1 time per week 2 or more times per day |
| About 1/4 of the time | |
| ○ About ¹/₂ of the time | 114a. Each time you ate other candy, how much |
| ○ About ³ /4 of the time | did you usually eat? |
| Almost always or always | |
| | Fewer than 2 pieces |
| 112c. How often were the pies you ate cream, | C 2 to 9 pieces |
| pudding, custard, or meringue pie? | More than 9 pieces |
| 3. | C. More than 5 pieces |
| Almost never or never | |
| ○ About ¹/₄ of the time | 115. How often did you eat eggs, egg whites, or egg |
| ○ About 1/2 of the time | substitutes (NOT counting eggs in baked goods and |
| O About ³ /4 of the time | desserts)? (Please include eggs in salads, quiche, and |
| Almost always or always | souffles.) |
| 112d. How often were the pies you ate pumpkin or | NEVER (GO TO QUESTION 116) |
| sweet potato pie? | |
| | |
| Almost never or never | 7-11 times per year 3-4 times per week |
| About 1/4 of the time | 1 time per month 5–6 times per week |
| About 1/2 of the time | 2–3 times per month 0 1 time per day |
| About 3/4 of the time | |
| About 1/4 of the time Almost always or always | 1 time per week 2 or more times per day |
| i runiost diways of always | |
| <i>!</i> | |
| reservor 113 apposins in the next column | Ourston for appears on the risia page (1) in the sign of the sign |
| | 23 |

On estion 10% upon ars in the next column.

Almost always or always

110 appears controlled hay :

| Over the past 12 months | 121b. What kind of non-dairy creamer did you |
|--|--|
| 119. How often did you add sugar or honey to your | usually use? |
| coffee or tea? | |
| | Regular powdered |
| NEVER (GO TO QUESTION 120) | Cow-fat or fat-free powdered |
| C NEVER (GO TO QUESTION 120) | C Regular liquid |
| (*) Logo than distance many (*) = 0.1 | Low-fat or fat-free liquid |
| Less than 1 time per 5-6 times per week | · · · · · · · · · · · · · · · · · · · |
| month 1 time per day | |
| 1-3 times per month 2-3 times per day | 122. How often was cream or half and half added to |
| 1 time per week 4–5 times per day | your coffee or tea? |
| 2-4 times per week 6 or more times per da | v : |
| · · | NEVER (CO TO OLICOTION 400) |
| 119a. Each time sugar or honey was added to you | r - |
| coffee or tea, how much was usually added? | |
| · | 0-0 times per week |
| C Less than 1 teaspoon | J' time per day |
| 1 to 3 teaspoons | |
| More than 3 teaspoons | 1 time per week 4–5 times per day |
| VI: | 2-4 times per week 6 or more times per da |
| | 1220 Foot Kanna |
| 120. How often did you add artificial sweetener to | 122a. Each time cream or half and half was adde |
| your coffee or tea? | to your coffee or tea, how much was usually |
| • | added? |
| NEVER (GO TO QUESTION 121) | |
| O 11211 (00 10 402011011 121) | Less than 1 tablespoon |
| C Less than 1 time per 5–6 times per week | 1 to 2 tablespoons |
| | More than 2 tablespoons |
| turie per day | |
| 4 | |
| 1 time per week 4–5 times per day | 123. How often was milk added to your coffee or tea? |
| 2-4 times per week 6 or more times per day | |
| 400-140-411-4-6-40-4 | NEVER (GO TO QUESTION 124) |
| 120a. What kind of artificial sweetener do you | |
| usually use? | Less than 1 time per 5–6 times per week |
| | month 1 time per day |
| Equal or aspartame | 1–3 times per month 2–3 times per day |
| Sweet N Low or saccharin | 1 time per week 4–5 times per day |
| ${\cal Y}$ | C 2-4 times per week |
| | o of more unles per da |
| 21. How often was non-dairy creamer added to your | 123a. Each time milk was added to your coffee |
| coffee or tea? | or tea, how much was usually added? |
| | to an indication was assaulty added: |
| NEVER (GO TO QUESTION 122) | C Less than 1 tablespoon |
| | 1 to 3 tablespoons |
| ○ Less than 1 time per ○ 5-6 times per week | More than 3 tablespoons |
| month 1 time per day | wiore than 3 tablespoons |
| (1–3 times per month 2–3 times per day | 193h M/hat bind of mile. |
| 1 time per week 4-5 times per day | 123b. What kind of milk was usually added to |
| 2-4 times per week 6 6 or more times per day | your coffee or tea? |
| of more times per day | 200 110 2 |
| 121a. Each time non-dairy creamer was added to | Whole milk |
| your coffee or tea, how much was usually | 2% milk |
| used? | 1% milk |
| useu: | ○ Skim, nonfat, or 1/2% milk |
| O Logo then 4 tonners | Evaporated or condensed (canned) milk |
| C 14a 2 1 | ○ Soy milk |
| 1 to 3 teaspoons | C Rice milk |
| | C Other |
| | |
| | $A = \frac{1}{2}$ |
| <i>(</i> | Market and the second s |
| to the 12. Apple as in the next cultime. | Constant: 24 appears in the courpage. |
| | 31 |
| | - · |



Question 13c appears on manager, a

HAT I'M SHOTHE MENT ON THE

| Over the past 12 months | 129b. How often was the cream cheese you ate light, low-fat, or fat-free cream cheese? |
|--|---|
| 127c. How often was the mayonnaise you | nging for facilities creatificitiesse? |
| ate fat-free mayonnaise? | Almost never or never |
| | ○ About ¹/₄ of the time |
| Almost never or never | ○ About 1/2 of the time |
| ○ About ¹/₄ of the time | About 3/4 of the time |
| About ¹ /2 of the time | Almost always or always |
| About ³ /4 of the time | |
| Almost always or always | |
| 128. Over the past 12 months, did you eat sour cream? | 130. Over the <u>past 12 months</u> , did you eat salad dressing? |
| | NO (GO TO INTRODUCTION TO QUESTION 131) |
| NO (GO TO QUESTION 129) | YES |
| () YES | |
| | |
| ¥ | 130a How often was the saled describe |
| 128a. How often was the sour cream you ate regular-fat sour cream? | 130a. How often was the salad dressing you ate regular-fat salad dressing (including oil and vinegar dressing)? |
| | |
| Almost never or never | |
| ○ About ¹/₄ of the time | About 1/4 of the time |
| About 1/2 of the time | ○ About ¹ / ₂ of the time |
| About ³ /4 of the time | About ³ / ₄ of the time |
| Almost always or always | Almost always or always |
| 128b. How often was the sour cream you ate light, low-fat, or fat-free sour cream? | 130b. How often was the salad dressing you ate light or low-fat salad dressing? |
| Almost never or never | Almost never or never |
| O About 1/4 of the time | About ¹ /4 of the time |
| About 1/2 of the time | About 1/2 of the time |
| About 3/4 of the time | 1 ! |
| Almost always or always | ○ About ³ /4 of the time ○ Almost always or always |
| V | Aimost always of always |
| 129. Over the past 12 months, did you eat cream cheese? | 130c. How often was the salad dressing you ate fat-free salad dressing? |
| | |
| NO (GO TO QUESTION 130) | About 1/4 of the time |
| | |
| () YES | About 1/2 of the time |
| | About ³ /4 of the time Almost always or always |
| ¥' | Airiost always of always |
| 129a. How often was the cream cheese you | |
| ate regular-fat cream cheese? | The following two questions ask you to summarize |
| | your usual intake of vegetables and fruits. Please do |
| Almost never or never | not include salads, potatoes, or juices. |
| About 1/4 of the time | potatodo, or juitod. |
| About 1/2 of the time | 131. Over the past 12 months, how many servings of |
| About ³ / ₄ of the time | vegetables (not including salad or potatoes) did you |
| Almost always or always | eat per week or per day? |
| | C Locathon 4 particles C 2 |
| | Less than 1 per week 2 per day |
| | 1–2 per week 3 per day |
| - 1 . i . | 3-4 per week |
| V | 5–6 per week 5 or more per day |
| Quadric 130 a, coars in the next corning | 1 per day |
| | .i 33 |
| | |

| Over | the <u>past 12 months</u> | |
|--|--|--|
| 132. | | s, how many servings of s) did you eat per week or |
| | Less than 1 per week 1–2 per week 3–4 per week 5–6 per week 1 per day | 2 per day3 per day4 per day5 or more per day |
| 133. | Over the <u>past month</u> , which did you eat AT LEAST 1 many as apply.) | nich of the following foods THREE TIMES? (Mark as |
| | Avocado, guacamole Cheesecake Chocolate, fudge, or butterscotch toppings or syrups Chow mein noodles Croissants Dried apricots Egg rolls Granola bars Hot peppers Jello, gelatin Milkshakes or ice-cream sodas | Olives Oysters Pickles or pickled vegetables or fruit Plantains Pork neckbones, hock, head, feet Pudding or custard Veal, venison, lamb Whipped cream, regular Whipped cream, substitute NONE |
| 134. | For ALL of the past 12 n any type of vegetarian c | nonths, have you followed liet? |
| | ○ YES ↓ 134a. Which of the follow | JDE from your diet? |
| Andreas and a second and and and and and and and and and a | Meat (beef, pork,○ Poultry (chicken,○ Fish and seafood○ Eggs○ Dairy products (m | turkey, duck) |
| i g Print militagraps sprats messes van de malante. | | |

The next questions are about your use of fiber supplements or vitamin pills.

| supp | plements or vitamin pills. |
|-----------|---|
| 135. | Over the <u>past 12 months</u> , did you take any of the following types of fiber or fiber supplements on regular basis (more than once per week for at least 6 of the last 12 months)? (Mark all that apply.) |
| | NO, didn't take any fiber supplements on a regular basis (GO TO QUESTION 136) YES, psyllium products (such as Metamucil, Fiberall, Serutan, Perdiem, Correctol) YES, methylcellulose/cellulose products (such as Citrucel, Unifiber) YES, Fibercon YES, Bran (such as wheat bran, oat bran, or bran wafers) |
| 7 136. | Over the <u>past 12 months</u> , did you take any multivitamins, such as One-a-Day-, Theragran-, or Centrum-type multivitamins (as pills, liquids, or packets)? |
| *** | ─○ NO (GO TO INTRODUCTION TO QUESTION 138) |
| Ţ. | - YES |
| 137. | How often did you take <u>One-a-day-, Theragran-, or Centrum-type</u> multivitamins? |
| | Less than 1 day per month 1-3 days per month 1-3 days per week 4-6 days per week Every day |
| | 137a. Does your multivitamin usually contain minerals (such as iron, zinc, etc.)? |
| | ○ NO○ YES○ Don't know |
| | 137b. For how many years have you taken multivitamins? |
| | Less than 1 year 1–4 years 5–9 years 10 or more years |





| Over the past 12 months | 139. How often did you take Vitamin A (NOT as part of a | | | |
|--|---|--|--|--|
| 137c. Over the past 12 months, did you take any | multivitamin in Question 137)? | | | |
| vitamins, minerals, or other herbal | protection (GO TO QUESTION 140) | | | |
| supplements other than your multivitamin? | I I | | | |
| | C Less than 1 day per month | | | |
| O NO | 1–3 days per month | | | |
| \forall | 1–3 days per week | | | |
| Y | ○ 4–6 days per week | | | |
| Thank you very much for completing this | Every day | | | |
| questionnaire! Because we want to be able to use all | | | | |
| the information you have provided, we would greatly | 139a. When you took Vitamin A, about how much | | | |
| appreciate it if you would please take a moment to | did you take in one day? | | | |
| review each page making sure that you: | | | | |
| | Less than 8,000 IU 15,000-24,999 IU | | | |
| Did not skip any pages. | ○ 8,000–9,999 IU ○ 25,000 IU or more | | | |
| Completely blackened-in each answer, and Completely arread arrest terms. | 10,000–14,999 IU Don't know | | | |
| Completely erased any changes you may have made. | | | | |
| A VEC (OO TO INTRODUCTION TO | 139b. For how many years have you taken | | | |
| QUESTION 138.) | Vitamin A? | | | |
| QUESTION 136.) | | | | |
| $igvee_{igvee}$ | C Less than 1 year | | | |
| These last questions are shout the vitamina minute. | ○ 1–4 years | | | |
| These last questions are about the vitamins, minerals, or herbal supplements you took that are <u>NOT</u> part of a | ○ 5–9 years | | | |
| One-a-day-, Theragran-, or Centrum-type of | ○ 10 or more years | | | |
| multivitamin. | ig ig | | | |
| | 110. How often did you take Mitage to 0 (110) | | | |
| Please include vitamins taken as part of an antioxidant | 140. How often did you take Vitamin C (NOT as part of a | | | |
| supplement. | multivitamin in Question 137)? | | | |
| | NEVER (GO TO QUESTION 141) | | | |
| 138. How often did you take Beta-carotene (NOT as part | O NEVER (GO TO GOESTION 141) | | | |
| of a multivitamin in Question 137)? | C Less than 1 day per month | | | |
| , | 1–3 days per month | | | |
| NEVER (GO TO QUESTION 139) | 1–3 days per week | | | |
| | 4-6 days per week | | | |
| Less than 1 day per month | C Every day | | | |
| ○ 1–3 days per month | | | | |
| ○ 1–3 days per week | 140a. When you took Vitamin C, about how much | | | |
| ◯ 4–6 days per week | did you take in one day? | | | |
| Every day | | | | |
| 400 1111 | C Less than 500 mg | | | |
| 138a. When you took Beta-carotene, about how | ○ 500–999 mg | | | |
| much did you take in one day? | ◯ 1,000–1,499 mg | | | |
| (2) 1 11 - 40 000 111 | ○ 1,500–1,999 mg | | | |
| Less than 10,000 IU | 2,000 mg or more | | | |
| ○ 10,000–14,999 IU | C Don't know | | | |
| . ① 15,000–19,999 IU | | | | |
| 20,000–24,999 IU | 140b. For how many years have you taken | | | |
| 25,000 IU or more | Vitamin C? | | | |
| O Don't know | | | | |
| 120h Fashaurran | () Less than 1 year | | | |
| 138b. For how many years have you taken | ○ 1–4 years | | | |
| Beta-carotene? | 5–9 years | | | |
| | 10 or more years | | | |
| Less than 1 year | | | | |
| ○ 1–4 years | | | | |
| ○ 5–9 years | | | | |
| 10 or more years | igwdot | | | |
| The same distriction and the same state of the s | Y | | | |
| Guestian 1 he appears in the next comme | Question 14) appears on the new rade. | | | |

Ourstran 14% appears on the new page. 35 ...

Nashville Men's Health Study

Vanderbilt University Medical Center Nashville, Th

For the Department of Defense Grant entitled 'Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer'

Please answer the questions below. We realize you may not know all of the answers to these questions, but please do the best you can and be as accurate as possible. It is OK to ask your friends or family for help, and you may refuse to answer any question.

All your information will be confidential, and used only for research.

Remember to bring this questionnaire to us at your clinic appointment. If you have any questions, or need another questionnaire, call Saundra Motley RN at 615-936-3418

| Subject # 🗆 🗆 | Subject In | Subject Initials | | | |
|---------------|------------|------------------|--|--|--|
| Your Name: | | | | | |
| Todays Date: | | | | | |

race, and occupation 1. Date of Birth: Month ____ Day ____ Year ___ Age ____ 2. What is your current marital status? (Select only one.) Married Living with a partner Widowed Divorced Separated □ Single, never married and not living with a partner 3. How much school have you completed? (Select only one) 8th grade or less More than 8th grade and less than high school High school □ Some College or a junior college degree (Associates, RN, etc) □ College (BA, BS, BSN, etc.) □ More than college completed (MA, MS, PhD, MD, JD, etc) 4. Are you presently employed? (Select only one.) ► GO TO Question #6 □ No. u Yes, employed full-time □ Yes, employed part-time → 5. If employed, how do you classify your job? (Select only one.) Skill or craft Machine operator Manual Labor Sales Scientific / Technical Service Clerical or office Professional, managerial, or administrative Performer, composer, or entertainer

First, a few questions about your date of birth, education,

| manu No | ifacturin o - GO es | es, what typ | yellow paii 1 # 7 | nts, etc.) | • | y | |
|------------|---------------------------|--|----------------------|------------|----------------------------|----------|--------|
| | best de | scribes the r | | | | | ox for |
| | White | African- American | Hispanic | Asian | Native- America | Other | |
| Mother | <u> </u> | American | | | America | | |
| Father | | | | | | | |
| · | Mo Fat | 'OTHER', j | | | | | |
| | - | | • | | · | | |
| | ledicare | /Tenncare | | | ıl / Indemn ı / POS /Op | - | нмо |
| c. H | | remicare | g. Non | | 17 1 03 70 ₁ | Jen ena | 111410 |
| d. P | | | h. Othe | | | | |
| 9. Have | you sm | ons about to toked at leas lifetime? | | | garettes, ci | gars, or | pipes |
| | fo – <i>GO</i> Tes | TO QUEST | rION #15 ase answer | #10 - # | 14 | | |

| 11. What did you smoke most (Select one only)? Cigarette Cigar Pipe |
|---|
| 12. Do you currently smoke?YesNo |
| 13. If you do not currently smoke, how old were you when you stopped smoking on a regular basis? years old. |
| 14. Now, or during the time you smoked regularly, how many cigarettes, cigars or pipefuls do you usually smoke: |
| On an average WEEKDAY (Monday - Friday)? On an average WEEKEND (Saturday - Sunday)? |
| Now we want to ask several questions about your family, and your family's health history. |
| 15. Were you adopted? □ No □ Yes |
| 16. Were you a twin, triplet, or other multiple birth? |
| No - GO TO Question # 19 Twin Triplet or other multiple birth |
| 17. Where you identical twins, triplets, etc?YesNo |
| 18. Was your twin or any of the others male? □ Yes – How Many Males? □ No |

| 19. How many brothers do you have? Please include only blood-related brothers with the same father and mother, and include all deceased brothers. |
|--|
| brothers (both living and deceased) |
| |
| 20. How many brothers does your mother have? brothers (both living and deceased) |
| 21. How many brothers does your <u>father</u> have? brothers (both living and deceased) |
| 22. Have any of your close male relatives ever had prostate cancer? I Don't Know No - GO TO Question # 24 Yes |
| 23. If Yes, which relatives: Father Brother Son Uncle Grandfather |
| 24. Have any of your close female relatives ever had breast cancer? □ I don't Know □ No - GO TO QUESTION # 26 □ Yes |
| 25. If Yes, which relatives: Father's Mother Mother's Mother Mother Sisters Aunts |

| • | NT | | | -14 | | | |
|-----|-----|------|---------------|-------------|----------|--------|---|
| | NOW | some | auestions | about | prostate | cancer | screening. |
| - 3 | | | 0 00 00 00 00 | | | | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ |

| 26. Have you ever had a PSA test (blood test to check for prostate cancer)? |
|--|
| □ No – Go to Question #28 |
| □ Yes ——— |
| 27. If Yes, how long ago did you last have a PSA test? Less than 1 year ago 1 to 2 years ago 3 to 5 years ago More than 5 years ago |
| 28. Have you ever had a rectal exam (that is, an exam in which the doctor checks your lower rectum with a finger)? • No - GO TO Question # 30 |
| □ Yes — |
| 29. If Yes, how long ago did you last have a rectal exam? Less than 1 year ago 1 to 2 years ago 3 to 5 years ago More than 5 years ago |
| Now several questions about your height and weight. |
| 30. What is the tallest you have ever been (without shoes)? feetinches |
| 31. How old were you when you were this tall?years old. |
| 32. How much did you weigh when you were born? If you are not sure, please provide your best guess: |
| pounds ounces |
| Please check this box if you can not provide a birth weight |

| 0 | oid you weigh less than 5 ½ poun Yes No Unsure | ds |
|-------|---|-------------------------------|
| | Oid you weigh 9 pounds or more Yes No Unsure | |
| 35. H | ow much did you weigh at each o | of the following times? |
| | a. Age 18 years: | _ pounds |
| | b. Age 30 years: | _ pounds |
| | c. Age 50 years: | _ pounds |
| | d. 5 years ago: | _ pounds |
| 36. W | hat has been the most you have e | ver weighed?pounds. |
| 37. H | ow old were you when you reache | ed this maximum adult weight? |

A few questions about how you are doing at this time.

38. Below is a list of statements. By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

| | Not at all | A little bit | Some- what | Quite a bit | Very much |
|--|------------------|--------------------|---------------|----------------|--------------|
| I am able to work (Include work at home) | 0 | 1 | 2 | 3 | 4 |
| My work (and work at home) is fulfilling | 0 | 1 | 2 | 3 | 4 |
| I am able to enjoy life | 0 | 1 | 2 | 3 | 4 |
| I have accepted my illness (if ill) | 0 | 1 | 2 | 3 | 4 |
| I am sleeping well | 0 | 1 | 2 | 3 | 4 |

| • | |
|---|--|
| | |
| | · |
| | |
| | |
| | all non-prescription medications, vitamin/mineral or other herbal supplements you use, and how often |
| | all non-prescription medications, vitamin/mineral or other herbal supplements you use, and how often |
| | |
| | |

Nashville Men's Health Study Physical Activity Assessment Interview

| Subject # DDD Subject In | itials 🔲 🔲 📗 |
|--|--|
| Date DD DD DD DD DD DD DD DD DD DD DD DD DD | |
| Current Occupation: I'd like to start by work status. | asking about your current |
| 1. Do you work outside the home, either volunteer? No – GO TO Question # 7 Yes | for pay or as a regular |
| 2. What is your main occupation or volume | iteer activity? |
| 3. How long have you had this job? | years |
| 4. {Classify this job: Circle the most ap this job, ask subject if need clarification | opropriate number to fit on job details} |
| 1 – low activity - White collar, cle 2 – moderate activity - plumbing, 3 – high-activity - Dock work, con | carpentry, farming, etc. |

5. When you are at this work place, how often do you do the following things?

| | Never | Seldom | Some times | Often | Always |
|--------------------|-------|--------|------------|-------|--------|
| sit | 1 | 2 | 3 | 4 | 5 |
| stand | 1 | 2 | 3 | 4 | 5 |
| walk | 1 | 2 | 3 | 4 | 5 |
| lift heavy objects | 1 | 2 | 3 | 4 | 5 |
| am tired | 1 | 2 | 3 | 4 | 5 |
| sweat | 1 | 2 | 3 | 4 | 5 |

6. In comparison with others of my own age I think my work is physically much heavier heavier as heavy lighter much lighter

CURRENT HOUSEHOLD ACTIVITY

Some questions about the activities you did in your home last week

- 7. Did you do light household work (dusting, washing dishes, mending/sewing)?
 - 0. Never
 - 1. Sometimes (only when partner or help not available)
 - 2. Mostly (sometimes assisted by partner)
 - 3. Always (alone or with partner)
- 8. Did you do heavy housework (washing floors, windows, carry trash)?
 - 0. Never
 - 1. Sometimes (only when partner or help not available)
 - 2. Mostly (sometimes assisted by partner)
 - 3. Always (alone or with partner)
- 9. For how many persons do you keep house, including self (fill in '0' if you answered 'never' to 7 and 8)
- 10. How many rooms did you keep clean, including kitchen, bedroom, garage, cellar, bathroom, attic, etc.

(fill in '0' if you answered 'never' in 7 and 8)

- 0. Never do housekeeping
- 1. 1 6 rooms
- 2. 7 9 rooms
- 3. 10 or more rooms
- 11. For the rooms that you clean, on how many floors are these rooms?
 _____ floors
- 12. Did you prepare warm meals yourself, or did you assist in preparing?
 - 0. Never
 - 1. Sometimes (once or twice a week)
 - 2. Mostly (3 5 times a week)
 - 3. Always (more than 5 times a week)

| stairs is 10 | y flights of stairs did you walk on a ty steps)? I never walk stairs | pical day (one flight of |
|-----------------------|--|--------------------------|
| 1 | . 1 - 5 | |
| 2 | . 6 - 10 | |
| . 3 | . More than 10 | |
| ; | | |
| 14. If you wen | nt somewhere in your hometown, what | t kind of transportation |
| | . I never go out | 6 |
| | . Car | |
| | . Public transportation | • |
| | . Bicycle | |
| | . Walking | |
| •• | · waiking | |
| 15 How often | did you go out for shopping? | |
| | . Never or less than once a week | |
| | Once a week | |
| | . Twice a week | |
| | . Every day | · |
| <i>J</i> , | . Every day | |
| 16 If you wan | at out for channing what him defended | |
| 10. II you well | at out for shopping, what kind of transp | portation did you use? |
| | . I never go out shopping | |
| | . Car | |
| | Public transportation | |
| | . Bicycle | |
| 4. | . Walking | |
| | | |
| | | · · |
| LEISURE TIM | ME ACTIVITY | |
| | | |
| 17. Did you pl | ay a sport or exercise last week? | |
| □ No – G0 | O TO Question # 20 | |
| Yes | | |
| | | |
| | | |
| 18. Mos | st Frequent Sport: | |
| | Hours/week | |
| M | Ionths per Year | |
| | | |

1,4

| 19. Next Freque Hours pe Months p | r week | | | The facility of the same of th | | |
|---|---------------------|--------------------|---|--|------------------------|-------------|
| 20. Did you have othe No - GO TO Q Yes | r physic uestion | cally activ #23 | e activit | ies last | week? | |
| 21. Most freque | ent activ | itv: | | | | |
| Hours pe | | , - | | | | |
| Months p | | | *************************************** | | | • |
| Wionino p | or rear | | | | | |
| 22. Next freque | nt Activ | vity: | | | | |
| Hours/we | | J - | | | | |
| Months p | er Year | | | | | |
| . | | | | | | |
| 23. During Leisure tin | ne: (<i>circ</i> | ele single i | most apr | propriat | e resnonsi | o) |
| | Never | | | Often | Always | ĺ |
| | | | times | OILLE | zzinajs | |
| I sweat | . 1 | 2 | 3 | 4 | 5 | 1 |
| I play a sport | 1 | 2 | 3 | 4 | 5 | |
| I watch television | 1 | 2 | 3 | 4 | 5 | |
| I walk | 1 | 2 | 3 | 4 | 5 | |
| I cycle | 1 | 2 | 3 | 4 | 5 | |
| 24. How many minute school, and shopping? | | | cycle po | - - | and from | ı work, |
| < 5 5-15 | 1 | .5-30 | 30-4 | 15 | > 45 minu | tes per day |
| 25. Do you regularly | attend (| at least 2 t | imes pe | r month |) a religio | us service? |
| | | | • | | | |
| □Yes | * | ∐No | | | | |
| 26. How many hours | a day di | d you usu | ally wat | ch telev | ision? | _hours/day |
| 27. In comparison to o | | ny physica more | | | g leisure ti less n | |

Thank you for completing this Questionnaire

Thank you for completing this questionnaire!

Please Bring it back to us!

Nashville Men's Health Study Interview Checklist

__Answer questions about study __Review eligibility

Consent form read and signed by subject and witness

Study ID Labels on all documents
Review medications/vitamins

Copy of consent form to subject

Diet history

Physical activity

Give subject diet report

Weigh Height

_Sitting height

Hips

Waist

Purple blood

Red blood

Urine collected

Collect mailed questionnaire

NMHS Form #5 Page 1 of 1 Nashville Men's Health Study Body Measurement

| H |
|-----------|
| Subject # |
| |

Subject Initials

Body Measurement

Measurements should be made without shoes and minimal clothing, such as underwear. Time: __:__ (_a.m.) or (_p.m.) <check one> Date:

Weight: _________ Height: ______ finches

_/4 inches

Sitting Height:

Waist

3) Waist: _____/2 inches

Hips: _____/2 inches

_/2 inches

Hips:

/2 inches

1) Waist:

/2 inches

2) Waist:

Instructions:

Use Gulich II tape measure, with sensing meter. Tape must be horizontal & not twisted

Waist: Measure at 2" above the navel. Narrowest part of the torso (see diagram)

Hips: Maximum posteria extension of buttocks

• Weight: Electronic scale, calibrated, no shoes

Height: No shoes; heels together; eyes straight ahead; compress hair

Sitting Height: Subject sits. Length from chair to top of head

Nashville Men's Health Study Biospecimen Collection

Subject Initials |

Subject # [

| Blood: Draw 2 tubes of blood (1 purple | | op EDTA and 1 red top serum). | · | Urine: Aliquot 9 aliquots: Discard remainder | liquots: Discard r | emainder |
|--|--|--|----------------|--|--------------------|----------------|
| Draw red tube first. | | ÷ | | Sample Obtained: | Date: | <u>Time:</u> |
| Sample Obtained | Date Drawn | Time Drawn | | Yes No | | |
| Yes No | | —————————————————————————————————————— | | Nambor of Aliquote | | A.M. P.M. |
| Tubes Drawn: | Name of Per | Name of Person drawing sample: | | Aliquots | | |
| Purple Red | | | | Comments: | | |
| Comments: | | , | | | | |
| | | | <u> </u> | | | |
| | | | | | | |
| | | | | | | |
| | | Proce | Processing Lab | | | |
| Date Blood Delivered | <u>Time:</u> | Delivered Samples: | # Aliquots | Time in Freezer | Freezer Box # | Freezer Shelf# |
| | —————————————————————————————————————— | Purple | Purple | AM PM | | |
| Initial for Receipt: | | Red | Red | •• | | |
| Date Urine Delivered: | <u>Time:</u> | | | AM PM | | |

NMHS Form #4 Page 1 of 1

Urine

Urine

AM PM

Nashville Men's Health Study Pathology & Prostate Cancer Screening History

| | | Other | | | , |
|----------------------------------|--------------|-----------------------|--|---|---|
| | 1 | SHBG | | | |
| | | Estradiol | | : | |
| (specify other) | | Testosterone | | | |
| Other (| | PPA | | | |
| VA Meharry Other (specify other) | | PSA (ng/ml) Free- PSA | | | |
| İ | - | PSA (ng/ml) | | | |
| Clinics:Vanderbilt | is: | Clinic | | | |
| • | Blood Analys | Date | | | |

DRE History:

| | | | | |
|---------------------------------|--------------------------------|-----|------|------|
| Firmness | | | | |
| Nodularity | | | | |
| Asymmetry Induration Nodularity | | | | |
| Asymmetry | | | | |
| Conclusion | (negative positive suspicious) | () | | |
| Clinic | | | | |
| Date | 3 | | | 4.5 |

| ıdy | |
|--------|------------|
| Stud | |
| Ith | |
| Health | |
| | ont. |
| Men's | [03] |
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| hv | h 0 |
| las | at |

| Subject # | Subject Initials |
|-----------|------------------|
| Subj | Subjo Date |

| į; | |
|----------|--|
| Results: | |
| Sound | |
| Iltra (| |

| | | | |
|---|-------------|---|------|
| Volume | | , | |
| Conclusion (negative, positive, suspicious) | | | |
| Clinic | | | |
| Date | | | · |

Biopsy History:

| Date | Clinic | # Cores Left | # Cores Left # Cores Right Total Cores | Total Cores | *Conclusion |
|------|--------|--------------|--|-------------|-------------|
| | | | , | | |
| | | | | - | |
| | | | | | |

^{*}Conclusion Options: Benign, Low-grade PIN, High-grade PIN, Suspicious, Invasive/CAP

| | | | | Subject # | |
|--|--------------------|---|-----------------------|------------------------|---|
| Nashville Men's Health Study Pathology (cont.) | ealth Study | | | Subject Initials Date | |
| HGPIN | Zone | | Dist | <u>Distribution</u> | |
| Yes | Peripheral | | | Focal | |
| % | Transition | | | Multifocal | |
| | Both | | | Extensive | |
| Invasive Cancer: | Stage | | <u>Gle</u> | Gleason | |
| Yes No | L | M | Score | Sum | |
| BPH Yes | Zone Peripheral | | Distribution Focal | ion | |
| No | Transition | | Multifocal | focal | - |
| | Both | | Extensive | ısive | |

NMHS FORM # 6 Page 3 of 3 February 20, 2003

«FirstName» «LastName» «Address1» «City» «State» «PostalCode»

Dear Mr. «LastName»,

You are invited to join the Nashville Men's Health Study. Prostate cancer is the most commonly diagnosed cancer in the United States, and we need your help to understand why prostate cancer is so common in Tennessee. To complete this study and to better understand the causes of prostate cancer, we have been given permission to contact men who recently received medical tests for prostate cancer at Vanderbilt or the VA.

The United States government has funded this research study, because so many men have prostate cancer and we do not understand why. It will be difficult to prevent prostate cancer or improve prostate cancer treatment without understanding the causes of this disease.

Even though you may not have prostate cancer, we need your participation. Your information will help us figure out how those men who have prostate cancer may differ from those men who do not have prostate cancer. In giving us your answers, you may be helping other men your own age and younger. You can make an important difference in helping to prevent prostate cancer by being involved in this study.

An interviewer from Vanderbilt University will be calling you. You have the right to decline this call. This introductory telephone call will take about 5 minutes, and we may ask you to visit our office at a convenient time to collect additional information. The interviewer will tell you more, and answer questions.

Cancer research relies on people to participate. We look forward to talking with you in the next couple of weeks. If you have any questions, please call Saundra Motley at 615-936-3418.

We are excited about this study and hopeful that you will participate.

Sincerely,

Dr. Joseph Smith Professor and Chair of Urologic Surgery Vanderbilt University Dr. Jay H. Fowke Assistant Professor of Medicine Vanderbilt University

Why Prostate Cancer Research?

Prostate cancer is the most common cancer diagnosis in the United States. Men living in the Southern United States are more likely to be diagnosed with prostate cancer than men living in other regions.

Why this study?

The Molecular Markers of Prostate Cancer Study is funded by Department of Defense (U.S. Army) through Vanderbilt University to study the possible role of hormones and diet in prostate disease.

Who Is Eligible

The study is open to men who are at least 50 years of age, received medical care at Vanderbilt, and live in Middle Tennessee.

What will be asked of Participants?

Study participants will come in for a visit to our office at Vanderbilt. Each participant will provide a blood and urine sample, and fillout a questionnaire. We will measure your weight and height, and ask you about the foods you usually eat. This visit will take about 1 hour, and we can schedule this meeting for a time of day convenient for you.

Location

Clinic visits will be held in the Clinical Research Center at Vanderbilt located in Medical Center North on the 3rd floor. Visitor parking is available next to this building.

What are the benefits of Participating?

As a participant in the study, you will have the opportunity to contribute to important research on preventing prostate cancer. Other people may receive future benefits from your participation. You may receive a summary of your information, and there will be no cost to you.

More Information

Please call:

Saundra Motley RN

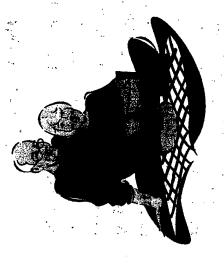
Project Coordinator

Center for Health Services Research

(615) 936-3418

E-mail:

Saundra. Motley @ Vanderbilt.edu

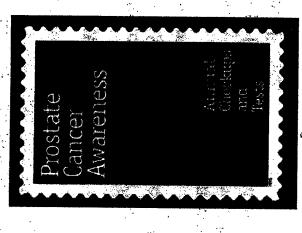


Why does Prostate Cancer Affect So Many People in Tennessee? NMHS Study by

Jay H. Fowke, PhD, MPH

Principal Investigator

Nashville Men's Health Study



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Nashville Men's Health Study

Telephone Script for Identification

For the Department of Defense Grant entitled 'Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer'

| (Greeting: Record who answers phone / man or woman) |
|---|
| My name is, and I am calling from Vanderbilt University Medical Center. |
| May we speak with <u>(subject's name),</u> please? |
| (If not available): That's fine. Is there a better time to call? |
| (Ask for better time to call back, record time, and call back at that time. Start at beginning of script.) |
| I hope I haven't taken too much of your time. Have a great (day/evening). Thanks again. (Hang-up) |
| (If Subect comes to telephone: repeat introduction) |
| Did you receive the letter I mailed you last week? |
| (If No, Confirm address. Tell him you will send letter immediately, and will call again next week. Thank subject. Hang-up.) |

We are conducting a study to understand how diet and physical activity may affect men's health and cancer risk. We are identifying men who have prostate cancer, as well as men who do not have prostate cancer. This telephone call will take only a few minutes, and I would like to tell you a little more about this study to see if you may be interested in taking part?

If no time, (either thank the participant for his time or enquire when would be a better time to call her back. Also record in the verification table of the ACCESS database the appropriate response and time to call back)

Otherwise, continue:

Page 1

Filename: PhoneSurvey_4v1

The findings of this study will be important because very little is known about what causes prostate cancer. Many lifestyle choices, including eating habits and physical activity levels, may be very important risk markers of prostate cancer. {Be ready to answer a few questions here- on published study results & role of estrogen in BC}.

We would like to schedule an appointment with our research nurse at our Vanderbilt clinic. This appointment may be scheduled at a time most convenient for you. During this visit, our nurse will measure your weight, height, and the circumference of your waist and hips. She will ask you several questions about the types of foods you usually eat, and about your activities.. After the interview, we will ask you to provide a urine sample and a blood sample. We estimate this visit will take about 1 hour. You will be given a summary of your dietary intake information, and this study will not cost you any money.

All of this information will be used for research purposes only, and all information will be kept confidential. No one other than the professors conducting the study will have access to your answers or the blood or urine samples. It is your decision whether or not you want to participate. Your participation will not benefit you or affect your healthcare, but may help other men in Tennessee by helping find the causes of prostate cancer.

Would you be interested in taking part in this study to investigate the causes of prostate cancer?

(If no, thank the participant for his time): That's fine. Thank you for your time and have a nice day. Good-bye.

(If Yes)

That's great. We appreciate your willingness to participate.

In order to qualify for this study, you must be at least 50 years of age, you must not have benign prostatic hypertrophy (BPH) (symptoms include weak or interrupted urine flow, painful urination, blood in urine, pelvic pain), you must have never been treated for prostate cancer, and you must not be taking any medications, such as Lupron or other drugs, that affects steroid or hormone levels. Do you think you qualify for this study?

(If YES to any question:) Thank you for your time. Unfortunately, you are ineligible for this study because..... Thank you again. Good bye.

(If NO to all questions: subject eligible. Continue)

Page 2

Filename: PhoneSurvey_4v1

It appears that you are eligible to take part in this research study. When would be a good time for you to do the interview- we will need about 1 hour.

(Begin schedule protocol: Name, address, date of visit, time of visit. Record all information, record telephone number)

Result of Recruitment: 1: recruited 2: not interested 3: ill 4: no time 5: no transportation 6: other:

I will send you a map a directions, as well as information about who to call if you need to re-schedule this appointment. If you have any questions before you receive my letter, feel free to call 615-936-2903. Saundra, our research nurse, will be expecting you. Don't for get to bring your parking ticket to this meeting for validation.

On behalf of the entire Nashville Men's Health Study research staff, I would like to thank you for participating in this study. Have a nice afternoon.

Answering Machine Protocol Hello, my name is ____ and I'm calling from Vanderbilt University Medical Center about a research study we are conducting. I will try to call back later. Thanks.

Page 3 Filename: PhoneSurvey_4v1 January 21, 2003

«Title» «FirstName» «LastName» «Address1» «City» «State» «PostalCode»

Dear «Title» «LastName»,

I am writing to thank you for taking part in our research study. As a participant in this study, your time and involvement was important to the success of our project. We plan to share the results of the study as soon as it is possible for us to do so.

I am enclosing the results of your dietary questionnaire. This is a summary of your average daily intake, based on your response to the dietary questions.

I have enjoyed meeting and working with you on the Nashville Men's Health Study. Please let me know if you have any questions by calling and leaving a message.

Sincerely,

Saundra Motley RN
Project Coordinator
Nashville Men's Health Study
Vanderbilt University
Telephone # 936-3418
Saundra.Motley@Vanderbilt.edu

Dr. Jay H. Fowke Principal Investigator Nashville Men's Health Study Assistant Professor of Medicine Vanderbilt University PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board Proposal for Research Using Human Subjects

Consent for Research Study

This consent form applies to all men undergoing diagnostic tests for prostate cancer.

| Name of subject | Age | |
|---------------------------------------|---|--|
| · · · · · · · · · · · · · · · · · · · | rm you about the research project and your participation in | |

The following information is provided to inform you about the research project and your participation in the study. Please read this form carefully. Please feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. You will be given a copy of this consent form.

1. Purpose of the study.

You are asked to participate in this study because you recently received a test for prostate cancer. The study investigates the role of hormones in prostate cancer development. Hormones, such as estrogens and androgens, cause prostate cells to grow and divide, potentially contributing to the formation of a prostate cancer. We have received funding from the Department of Defense (U.S. Army) to investigate how these hormones could influence prostate cancer formation. We will enroll men with prostate cancer and men without prostate cancer, and compare the amounts of these hormones between these groups. This study may help us to understand why some men develop prostate cancer while others do not, and to develop new approaches to prevent prostate cancer.

2. Description of the procedures to be followed and approximate duration of the study.

We will ask you to visit our office at Vanderbilt University Medical Center for about 1 hour. This office visit can be scheduled for a day convenient to you. During this visit, we will collect a sample of blood (about 5 teaspoons) in the usual way, by inserting a needle into a vein in your arm. We will use this blood sample to determine levels of the hormones that are thought to be important in modifying prostate cancer risk, and we will identify enzymes responsible for breaking-down these hormones. We will collect a smal (about 3 ounce) urine sample. This urine sample will be used to determine the levels of additional hormones that are excreted from your body in your urine. Our blood and urine measurements may be affected by tobacco, weight, diet, and perhaps other factors. If you use tobacco, it is important these urine and blood samples be collected at least 2 hours after your last cigarette, cigar, or pipe. We will

measure your weight, height, the circumference of your waist and hips, and we will ask you about the types of foods you typically eat and your exercise habits. We will give you a summary of your dietary information when it is possible to do so.

In summary, your research office visit will include:

- A blood sample
- A urine sample
- Weight and height measurements
- Questions about your diet and activities
- Waist and Hip Measurements

Your medical records will be reviewed to determine eligibility. The project coordinator will collec demographic, medication, and pathology information.

At this interview, we will give you a questionnaire that contains questions about several topics such as you education, job, and date of birth. This questionnaire will require about 20 minutes, and we will ask you to complete the questionnaire at home and mail it back to us in a postage-paid envelope, which we provide.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

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Vanderbilt University Institutional Review Board Proposal for Research Using Human Subjects

Consent for Research Study

You may be removed from the study if you are found to be no longer eligible in the study or if you are unwilling or unable to provide the information we request.

3. Possible discomforts, inconveniences, and/or risks

Drawing blood may hurt slightly, and you might have a black and blue mark. Occasionally a person may become dizzy or faint when blood is drawn and there is a rare possibility of infection or temporary nerve damage. You may collect your urine sample in a nearby bathroom for privacy. There should be no risk or discomfort when we measure your weight or height, ask questions about your diet or physical activities.

If you are injured as a direct result of participating in this research project, you will be provided with medical care at no cost to you for that injury. You will not receive any injury compensation, only medical care. This is not a release of your legal rights, and you should discuss this with investigators before enrolling.

All questionnaires and other information you provide will kept confidential. Documents will be stored in locked rooms and cabinets, accessible only to the study investigators. A study ID number will be assigned to each volunteer, and all your documents will be labeled only with this study ID number. Only the project manager and principal investigator will be able to break this code. Our analysis compares groups of study participants, and no information about an individual study participant will be released or reported. The documents will be shredded and destroyed when they are no longer needed for research purposes, and always no longer than 20 years from collection.

4. Benefits resulting from this study

There are no direct benefits to you for participating in this study. Other than what is specifically stated in this consent form, there is no compensation. The knowledge gained from your participation in this research may help further our understanding of how to prevent or treat prostate cancer.

5. Alternative procedures

You may choose not to take part in this study. You may choose not to answer certain questions or may contact the principal investigator at 615-936-2903 if later you decide to have your samples or questionnaires destroyed.

6. Contact information:

If you should have any questions about this research study, please feel free to contact Dr. Jay H. Fowke at 615-936-2903. For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866-224-8273). If you are participating in a research project at the VA Medical Center, please contact the Research and Development office at (615) 327-5346.

OCT 03 2003 1

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board Proposal for Research Using Human Subjects

Consent for Research Study

7. Sample Donation

One risk of donating samples for genetic research may be the release of information (for example your name) that could link you to the stored samples and/or the results of the tests run on your samples. The release of this information that identifies you could cause problems with insurance or future employment. There are many safeguards in place to prevent the release of information from this study.

All samples obtained for this study will be assigned a study ID number. The key to the study ID number will be kept in a locked file in the investigator's office. Only the Principal Investigator (Dr. Jay H. Fowke) and the study coordinator will have access to the code and information that identifies you as a being in this study. The results of tests run on your samples will not be recorded in your records and neither you, nor your doctor will be told of the results. No one else, including relatives, doctors, employers or insurance companies will be allowed to view your test results.

Your blood and urine samples will be used only for research and will not be sold or used directly to produce products that could be sold for money. The cells, proteins, DNA or other materials from your samples, as well as the results of genetic testing and other data about you, may be shared with other researchers for research purposes. Personal information may also be shared (such as your age, sex and illness) but the samples will not be labeled with your name, address or other information that would identify you. All information will be coded to maintain your privacy. At the end of the study, the codes used to identify your samples will be destroyed. There will be no cost to you for any of the tests your samples are used for. You will not be paid to have these tests performed.

These blood and urine samples will be used to investigate the relationship between hormones and hormone metabolism in prostate cancer. However, cancer research often advances in unexpected directions, and the DNA from your samples may also be used in future studies for purposes that are currently unknown. These future studies most likely will be related to prostate cancer, but it is possible these studies may be related to other diseases. The samples you donate will be will be destroyed when they are no longer needed, and always within 20 years of collection.

There is a chance that the samples that you are donating under this study may have some commercial value, however no commercial value is anticipated. Should your donated samples lead to the development of a commercial product, Vanderbilt University will own it and may take action to patent and license the product. Vanderbilt does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of your samples.

Date: November 4, 2002

PI: Jay H. Fowke, Ph.D.

Date: November 4,
Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board Proposal for Research Using Human Subjects

Consent for Research Study

| Please check Yes may continue to | or No, and sign to indicate participate in this study rega | that you have freely given conser rdless of which level of participation | nt for sample donation. On you choose. | You |
|----------------------------------|--|---|---|-----|
| My blood sample | may be used for genetic tes | ting in association with this prosta | te cancer study. | |
| ☐ Yes | □No | | | |
| My blood sample | e may be stored for future ge | netic research in prostate cancer. | | |
| ☐ Yes | □No | | | |
| | sample may be stored/shared xample, diabetes, heart disea | d for future genetic research involuse, etc). | ved with other medical | |
| ☐ Yes | □No | | | |
| | sented with a form much li | ask you to participate in other si ke this one that will explain the | | |
| | | | | |
| | Parti | icipant Signature for Sample Dona | tion | |
| | | | | |

PI: Jay H. Fowke, Ph.D.

Date: November 4, 2002

Title: Molecular Markers of Estrogen Metabolism and Progression from High-Grade Prostatic Intraepithelial Neoplasia (HGPIN) to Prostate Cancer

Institution: Vanderbilt University Medical Center

Vanderbilt University Institutional Review Board Proposal for Research Using Human Subjects

Consent for Research Study

Your rights as a volunteer:

Your participation in this study is voluntary, and you may choose not to participate. You are not waiving your legal rights, or releasing any agent from liability or negligence. You are also free to withdraw from this study at any time. Withdrawal or refusal to participate will not prejudice your health care.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

Efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. The U.S. Army Medical Research and Material Command reserves the right to audit the records of this study for quality assurance and protocol compliance.

Signature

Printed Name and Title

| The material cont been answered, and time. | ained in I freely | this consent form has been explained and voluntarily choose to participate | to me verbally. All my . I understand that I m | questio nay with |
|--|---------------------------------------|--|---|---------------------|
| Date | | Signature of Volunteer | | • |
| | | | | |
| | | | | |
| | , , , , , , , , , , , , , , , , , , , | Address of Volunteer | | |

Consent obtained by:

VA RESEARCH CONSENT FORM

| Subject Name: | Date: |
|---|---|
| Title of Study: Nashville Men's Health Study | |
| Principal Investigator: <u>Jay H. Fowke, PhD</u> | VAMC: Nashville |
| The following information is provided to inform you about the reservence read the form and feel free to ask any questions you may have below. You will be given the opportunity to ask questions and have making a decision to participate in this study. You will be given a | ve about the information provided re your questions answered before |
| URPOSE OF THE STUDY | |
| ou are asked to participate in this study because you recently received investigates the role of hormones in prostate cancer development of the prostate cells to grow and divide, potentially contributed. We have received funding from the Department of Defense commones could influence prostate cancer formation. We will enroll without prostate cancer, and compare the amounts of these hormone may help us to understand why some men develop prostate cancer we perpoaches to prevent prostate cancer. | ent. Hormones, such as estrogens and ibuting to the formation of a prostate (U.S. Army) to investigate how these men with prostate cancer and men s between these groups. This study |
| ESCRIPTION OF THE PROCEDURES AND APPROXIMA | TE DURATION OF THE STUDY |
| We will ask you to visit our office at Vanderbilt University Medical can be scheduled for a day convenient to you. During this visit, we about 5 teaspoons) in the usual way, by inserting a needle into a verample to determine levels of the hormones that are thought to be in isk, and we will identify enzymes responsible for breaking-down the weight collect a small (about 3 ounce) urine sample. This urine saw evels of additional hormones that are excreted from your body in your easurements may be affected by tobacco, weight, diet, and perhap important that this urine sample be collected at least 2 hours after your will measure your weight, height, the circumference of your was about the types of foods you typically eat and your exercise habits. | will collect a sample of blood in in your arm. We will use this bloomportant in modifying prostate cancenese hormones. If you use tobacco, it our last cigarette, cigar, or pipe. ist and hips, and we will ask you |
| BJECT'S IDENTIFICATION (I.D. plate of given name - last, first, middle) | |
| | |
| | |
| VA FORM JAN 1990 10-1086 IRB Approval Date: 100 IRB Expiration Date: 103 2005 | ••• |
| IAN 1990 TU-1U80 | |

VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 2)

| Subject Name: | Date: | | | |
|--|--|--|--|--|
| Title of Study: Nashville Men's Health Study | | | | |
| Principal Investigator: <u>Jay H. Fowke, PhD</u> | VAMC: Nashville | | | |
| Your medical records will be reviewed to determine eligibility demographic, medication, and pathology information. | /. The project coordinator will collect | | | |
| At this interview, we will give you a questionnaire that contain your education, job, and date of birth. This questionnaire will you to complete the questionnaire at home and mail it back to provide. | require about 20 minutes, and we will ask | | | |
| You may be removed from the study if you are found to be no unwilling or unable to provide the information we request. | longer eligible in the study or if you are | | | |
| In summary, your research office visit will include: | | | | |
| A blood sample A urine sample Weight and height measurements Questions about your diet and activities A questionnaire to take home, and mail back to us | | | | |
| DESCRIPTION OF THE DISCOMFORTS, INCONVENII Drawing blood may hurt slightly, and you might have a bit person may become dizzy or faint when blood is drawn and the temporary nerve damage. You may collect your urine sample should be no risk or discomfort when we measure your weight or physical activities. | lack and blue mark. Occasionally a here is a rare possibility of infection or in a nearby bathroom for privacy. There | | | |
| All questionnaires and other information you provide will be stored in locked rooms and cabinets, accessible only to the st be assigned to each volunteer, and all of your documents will Only the project manager and the principal investigator will be compares groups of study participants, and no information at released or reported. The documents will be shredded and de research purposes, and always no longer than 20 years from one of the compared of the purposes. | udy investigators. A study ID number will be labeled only with this study number. be able to break this code. Our analysis bout an individual study participant will be stroyed when they are no longer needed for | | | |
| | Cubiasta Taitiala | | | |
| ell It. | Subject's Initials | | | |
| VA FORM JAN 1990 10-1086 PROF. 100 100 100 100 100 100 100 100 100 10 | 3 | | | |

VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 3)

| Subject Name: | Date: |
|--|-----------------|
| Title of Study: Nashville Men's Health Study | |
| Principal Investigator: Jay H. Fowke, PhD | VAMC: Nashville |

For study participants who are veterans:

As a veteran subject you will not be required to pay for any treatment received as a research subject, which is being done solely for the purpose of this research study. However, your insurance carrier will be billed for all routine care and clinical procedures, if applicable. If you are in a "priority group # 7 veteran category" you are subject to making a co-payment as indicated by a means test. Your doctor should be able to provide you with this information or refer you to the appropriate individual for any questions you may have. As a veteran, you will receive medical care and treatment for injuries suffered as a result of participating in a VA research program in accordance with Federal Law. You will incur no additional charges for additional medical care that may result from injury or complications that are a direct result of your participation in this study.

ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION

There are no direct benefits to you for participating in this study. Other than what is specifically stated in the consent form, there is no compensation. The knowledge gained from your participation in this research may help others, by furthering our understanding of how to prevent or treat prostate cancer.

ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE

You may choose not to take part in this study. Your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment, if you are a patient. You may choose not to answer certain questions or may contact the principal investigator at 615-936-2903 if later you decide to have your samples or questionnaires destroyed.

CONTACT INFORMATION

If you should have any questions about this research study, please feel free to contact Dr. Jay H. Fowke at 615-936-2903. For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or the Research and Development Office at (615) 327-5346.

| | | Subject's Initials _ | | |
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VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 4)

| Subject Name: | Date: |
|--|-----------------|
| Title of Study: Nashville Men's Health Study | |
| Principal Investigator: <u>Jay H. Fowke, PhD</u> | VAMC: Nashville |

RESEARCH RESULTS

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study. If results of this study are reported in medical journals or at meetings, you will not be identified by name, or by any other means without your specific consent.

CONFIDENTIALITY AND PRIVACY

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators, the sponsor (when applicable), and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties.

STORING SAMPLES AND GENETIC SCREENING OF STORED SAMPLES

The purpose of this part of the study is to store for future use samples of your blood to look for genetic factors (DNA) that may cause or relate to prostate cancer or other conditions or illnesses. This blood sample is the same sample described in section 2 above.

One risk of donating samples for genetic research may be the release of information (for example your name) that could link you to the stored samples and/or the results of the tests run on your samples. The release of this information that identifies you could cause problems with insurance or future employment. There are many safeguards in place to prevent the release of information from this study. All samples obtained for this study will be assigned a study ID number. The key to the study ID number will be kept in a locked file in the investigator's office. Only Dr. Jay H. Fowke and the study coordinator will have access to the code and information that identifies you as a being in this study. The results of tests run on your samples will not be recorded in your records and neither you, nor your doctor will be told of the results. No one else, including relatives, doctors, employers or insurance companies will be allowed to view your test results.

| | | | Subject's Initials |
|-------------------------------------|----------------------|-----------------|--------------------|
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| JAN 1990 10-1086 IRB Approval Date: | IRB Expiration Date: | RB Chair Initia | als: MOR_ |

VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 5)

| Subject Name: | Date: |
|--|-----------------|
| Title of Study: Nashville Men's Health Study | |
| Principal Investigator: Jay H. Fowke, PhD | VAMC: Nashville |

Your blood and urine samples will be used only for research and will not be sold or used directly to produce products that could be sold for money. The cells, proteins, DNA or other materials from your samples, as well as the results of genetic testing and other data about you, may be shared with other researchers for research purposes. Personal information may also be shared (such as your age, sex and illness) but the samples will <u>not</u> be labeled with your name, address or other information that would identify you. All information will be coded to maintain your privacy. At he end of the study, the codes used to identify your samples will be destroyed. There will be no cost to you for any of the tests your samples are used for. You will not be paid to have the tests performed.

These blood and urine samples will be used to investigate the relationship between hormones and hormone metabolism in prostate cancer. However, cancer research often advances in unexpected directions, and the DNA from your samples may also be used in future studies for purposes that are currently unknown. These future studies most likely will be related to prostate cancer, but it is possible these studies may be related to other diseases. The samples you donate will be will destroyed when they are no longer needed, and always within 20 years of collection.

There is a chance that the samples that you are donating under this study may have some commercial value. No commercial value is anticipated. Should your donated samples lead to the development of a commercial product, Vanderbilt University will own it and may take action to patent and license the product. Vanderbilt does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of your samples.

| | | Subject's Initials | ·. |
|-------------------------------------|-------------------|--------------------------|----|
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VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 6)

| Subject Name: | · | | _ Date: |
|---|--|--|---|
| Title of Study: | Nashville Men's H | ealth Study | |
| Principal Invest | igator: <u>Jay H. Fo</u> v | wke, PhD | VAMC: Nashville |
| Please check to consent: | Yes or No and sign you | r name, indicating yo | ou have freely given your answers and |
| My blood/tiss | ue sample may be used | for genetic testing in | association with this study. |
| Yes | □ No | | |
| My blood/tiss cancer. | ue sample may be store | ed/shared (if applicab | le) for future genetic research in prostate |
| Yes | No | | |
| My blood/tisso with other medica disease, etc). | ue sample may be store Il conditions (for examp | ed/shared (if applicable, obesity, diabetes, | le) for future genetic research involved cancer, heart disease, Alzheimer's |
| ☐ Yes | □ No | , | |
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VA RESEARCH CONSENT FORM

(Date: November 4, 2002 /Continuation Page 7)

| Subject Name: | Date: |
|--|--|
| Title of Study: <u>Nashville Men's Health Stud</u> Principal Investigator: <u>Jay H. Fowke, PhD</u> | VAMC: Nashville |
| STATEMENT OF PERSON AGREEING TO PAR | TICIPATE IN THIS RESEARCH STUDY |
| I have read () this consent form or have had it read t | o me (). |
| has explained the study to me and been told of the risks or discomforts and possible benefitreatment available to me. | all of my questions have been answered. I have fits of the study. I have been told of other choices of |
| If I do not take part in this study, my refusal to particip, which I am entitled. I may withdraw from this study at benefits to which I am entitled. | |
| I have been told my rights as a research subject, and I we have been told what the study is about and how and what answered. | |
| I will receive a signed copy of this consent form. | |
| Subject's Signature | Date |
| Signature of Subject's Representative*/Relationship | Date |
| Signature of Witness | Date |
| Signature of Investigator | Date |
| *Only required if subject not competent. | |
| | |
| | Subject's Initials |
| VA FORM | Subject 5 Matters |
| IRB Approval Date: IRB Expiration Date: | IRB Chair Initials: MOR |

Informed Consent

Informed consent is a process, not just a document that human subjects sign. The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45CFR 46.117. Information will be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Explanation will be designed to educate the participant in terms that they can understand. The written presentation of information is used to document the basis for consent and for the subjects' future reference. Informed consent is not an isolated point in time that ends upon the subject signing the form. The process of informed consent continues during the entire relationship of the participant to the research project.

Procedure:

- The consent form used will have date of IRB approval
- The informed consent will be obtained at Visit 1, the in-person interview
- Make sure the participant is comfortable
- Consider the educational and emotional state of the participant
- Provide adequate time for the participant to consider the information
- Confidentiality
- Written approval of release of information
- Explain the study to the participant including:

Clinical protocols

- Urine sample
- Blood sample

Questionnaires

- Dietary History
- Activity

Measurement procedures

- Answer participant questions
- Sign Consent
- Provide participant with copy of signed document
- Original to be kept in patient study file

Patient Identification and Confidentiality

Confidentiality

Throughout the study, standard measures to ensure privacy and information on study subjects will be maintained. Subjects will be informed that all information will be confidentially held, and assured that data will be used only for statistical purposes. Individuals will not be identified in the analysis. No data beyond what is stated in the informed consent will be sought without authorization from the subject or next of kin. Information on hospitalization or illness will not be sought from hospitals or doctors without a signed medical release from the subject. No information on any individual will be released to anyone other than study personnel without the written approval of the individual or, where appropriate, the next of kin or physician in the case of a life-threatening situation. All study personnel will be instructed not to discuss any cases with persons other than study personnel.

Identification Protocols

Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#

The numbers will be assigned in sequence 001,002,003, and so on

Patients will retain the same number throughout the study

All specimen will have NMHS =Nashville Men's Health Study All specimen will have the patient ID# and an alpha code All Specimens will have a letter on the label to indicate source

U=urine
G=Genetic
S=Serum and Blood Clots

Duplicate of label will be placed on Biospecimen Collection Form

Example ID # 001 XYZ U would denote patient 1, Urine All specimens would be labeled using this identification system

ADVERSE EVENTS

Introduction

Only subjects with ongoing doctor/patient relationships will be used in this study. Patients will continue their usual care with their physician(s). Telephone numbers for the study PI and study coordinator will be given to the subject. Any problems discovered by the study team will be discussed at an appropriate level with the patient sufficient to affect referral to the patient's primary care physician who will also be informed after written consent by the patient.

Adverse event is defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a treatment or procedure regardless of whether it is considered related to the treatment or procedure. Examples of adverse events are:

- Death
- A Life-Threatening Condition
- A Cancer
- A PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY (substantial disruption of one's ability to conduct normal life functions)
- A Hospitalization (includes an overnight stay, regardless of length of stay, even if the hospitalization is a precautionary measure for continued observation)
- Prolonged an existing inpatient hospitalization. NOTE: Hospitalization for a pre-existing condition, which has not worsened, does not constitute a serious experience.
- A congenital anomaly/birth defect (in offspring of subject taking the product, regardless of time of diagnosis)
- An overdose (whether accidental or intentional)

Throughout the study, we will closely monitor for adverse events. Side effects are monitored in several ways.

- Participants have the telephone numbers of the project coordinator and the principal investigator, and are encouraged to call if necessary.
- Participants also may e-mail study personnel.
- Participants will be instructed to write-down any side effects or unusual events, and bring these notes to a clinic visit

All project staff consult with the principal investigator and physician co-investigator about all side effects reported by subjects. All potential side effects are rated as mild, moderate, or severe. The project coordinator handles minor side effects, after consultation with the PI and Co-I. Moderate or severe events will be recorded on a adverse event form. This form includes a summary of the adverse clinical event, an assessment of the likelihood that the event was due to protocol, and a statement of action taken. These forms remain as part of the participant's file. The PI and physician Co-I will be responsible for stopping the study if needed. The intervention phase, last only for the clinic visit in which blood is drawn.

Adverse events will be reported to the Vanderbilt IRB as required by protocol.

Questionnaires

Identification Protocols

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1

All questionnaires will have the patient identification number.

Assigning a birth date of 06/01 and the patient's year of birth for age analysis will protect patient age information.

Procedure

A questionnaire will be provided to subjects either at the clinic visit or mailed to their home prior to the dietary interview. It is designed to collect basic demographic and health information, such as age, race, occupation, and family history of cancer and physical activity. It is possible that subjects may need to ask spouses or family members for help in recalling this information, and therefore accuracy may be improved by providing participants a few days to complete this mailed questionnaire. Additionally, completion of the questionnaire at the subject's home decreases the time of the interview. Subjects will be asked to return the questionnaire in a postage paid envelope or bring to the interview session. Up to three reminder calls will be placed to the subject in the event that the subject does not return the questionnaire promptly, and subjects will be provided the additional options of returning the questionnaire in person or having a research associate pick it up at their home or place of business.

Habitual physical activity will be measured using a modified version of the Baecke index, designed to capture the physical activities of older people. This questionnaire includes questions that cover three components of physical activity: physical activity at work, sports during leisure time, and physical activity during leisure time excluding sports.

Habitual dietary intake will be measured by interview to capture a wide range of usual eating patterns, cooking practices, supplements, herbs, and vegetables during the past year. The FFQ is the Diet History Questionnaire developed at the NIH and recently validated against alternative questionnaires and assessment approaches.

The diet questionnaires are administered by in person interview. During the interview, the research nurses asked whether or not the participant eats a certain food, and the frequency that food is consumed. Similarly, each activity is asked. Paper versions of these questionnaires were included in this protocol for the review, however subjects will not see this paper version. Men, in general, do not complete dietary questionnaires as reliably as women, and therefore an inperson interview for these difficult questionnaires is necessary to obtain reliable information.

Peripheral venous blood

Identification

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1
All specimens would be labeled using this identification system

Peripheral venous blood will be collected using standard sterile procedures.

One 5ml (ethylenediamine-tetraacetic acid or EDTA) will be for a source of DNA

Two 5 ml (no anticoagulants) will be collected for radioimmunoassay for E2 (Serum estradiol)

The EDTA tube of blood will be transported to the PHG DNA core lab in room 518 Light Hall for DNA extraction. Contact: Cara Sutcliffe, ext 6-2744

The remaining two 5 ml vials of blood will be allowed to clot and centrifuged. The serum will be pipetted into a maximum of 9 equal amounts in 1.8 crovials. The remaining clots will also be retained and frozen at –80 degrees.

The specimens will be transported and analyses will be conducted at the Molecular Epidemiologic Research Laboratory directed by Dr. Quiyin Cai located at the Vanderbilt-Ingram Cancer Center. Dr. Fritz Parl in Medical Pathology at Vanderbilt University will oversee estrogen analysis on blood and urine specimens.

The biospecimens collected in this protocol will be stored frozen for up to 20 years, and additional laboratory tests may be performed on remaining biospecimens in order to further explain our study results or to develop subsequent protocols. At the end of this period, samples will be destroyed, and all paper documents will be shredded and destroyed.

Urine Collection

Identification

To maintain confidentiality and to meet HIPPA standards of PHI, the patient will be identified by use of an ID#. Each patient will be assigned a numerical identification number for confidentiality purposes. The patient's initials will also be part of the ID#. The numbers will be assigned in sequence 001,002,003, and so on. Patients will retain the same number throughout the study.

Example ID # 001 XYZ would denote patient 1
All specimens would be labeled using this identification system

A urine sample at least about 20 mls, will be collected. Two ml aliquots of urine will be dispensed into each of nine labeled (ID #) freezer tubes and stored at – 80°C until assayed for estrogen. Urinary 2HE, 4HE, and 16HE metabolite levels will be measured. Smoking participants will be asked not to smoke for a two-hour period prior to the visit, to reduce the impact of aromatic hydrocarbon exposure on estrogen metabolism.

Procedure

Preparation:

9-1.8ml cryovials vials Specimen box Labels Permanent markers Biohazard Bags

At the clinic visit, participants will be given:

Urine containers

Urine Processing

- Urine specimens will be stored in CRC refrigerator
- Specimens will be processed after participant visit
- All specimen's will be labeled with date, participant ID #
- 1-2 ml aliquots of the urine sample will be pipetted into each of 9-labeled cryovials.
- Vials will be placed in specimen box for storage
- Remaining specimen will be discarded
- Study staff will then transport specimens to Dr. Qiuyin Cai MRB II, 618, ext # 6-1351
- Date, time and location of sample in the freezer will be recorded on the specimen log
- Samples will be stored at -80° C.
- Urine specimens will be stored until ready for analysis.

Measurement Protocols

Procedure

Collect data at 1 time-point during the study:

Body circumferences will be measured at initial clinic visit. Height and weight will be collected. A sitting height will also be collected.

Body mass index (weight (kg)/height (m)²) and the waist-to-hip ratio will be calculated. Body mass index (BMI) is a measure of body fat based on height and weight that applies to both adult men and women. Inches will be converted into millimeters and pounds into kilograms.

Height:

- 1. Height will be measured at initial clinic visit.
- 2. Height will be measured with out shoes and recorded in inches

Sitting Height:

- 1. Sitting height gives a measure of the trunk. It is a measurement of the distance from the highest point on the head to the base-sitting surface. Height measurement can vary throughout the day, being higher in the morning, so should be measured at a consistent time of day.
- 2. The subject sits with both feet on the floor, the lower back and shoulders straight and in alignment looking straight ahead. The height is measured form the surface of the chair to the highest point on the head.

Body weight:

- 1. Body weight will be measured at initial clinic visit.
- 2. Weight without shoes will be measured using calibrated scales and recorded in pounds

Participant's hip and waist circumferences will be measured in light clothing using a Gullick 2 tape measure. The circumference measures will be collected twice, and repeated if disparity between these two measures is greater than 10%.

- 1. Patient should be wearing loose fitting clothing.
- 2. Patient should be standing and breathing quietly with legs together and arms at sides leaving enough room to get the tape measure around the body

Waist:

- a. Measure the torso one inch above the navel even if this is not the usual waist line. Be sure that the tape is snug and horizontal and measure from the side. Make sure that fingers are not under the tape measure
- b. Record the first measure to the nearest half inch. If the measure is equal to a quarter inch, ¼ or ¾, then round downward
- c. Remove the tape measure and begin again for the second measurement.

d. Record the second measurement in the same manner as the first. If the two measurements are not within one inch of each other, then the entire process should be repeated and the two **new** measurements recorded

Hips:

- e. Measure the hips at the largest spot between the waist and thighs. This can be found by sliding the tape measure up and down. Be sure that the tape is snug and horizontal and measure from the side. Make sure that fingers are not under the tape measure
- f. Record the first measure to the nearest half inch If the measure is equal to a quarter inch, ¼ or ¾, then round downward
- g. Remove the tape measure and begin again for the second measurement.
- h. Record the second measurement in the same manner as the first. If the two measurements are not within one inch of each other, then the entire process should be repeated and the two **new** measurements recorded.